

Exhibit 1



US005922021A

United States Patent

[19]

[11] Patent Number: **5,922,021**

Jang

[45] Date of Patent: ***Jul. 13, 1999****[54] INTRAVASCULAR STENT**[76] Inventor: **G. David Jang, 30725 Eastburn La., Redlands, Calif. 92374**

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/845,657**[22] Filed: **Apr. 25, 1997****Related U.S. Application Data**

[63] Continuation-in-part of application No. 08/824,142, Mar. 25, 1997, application No. 08/824,866, Mar. 25, 1997, and application No. 08/824,865, Mar. 25, 1997

[60] Provisional application No. 60/017,484, Apr. 26, 1996.

[51] Int. Cl.⁶ **A61F 2/06**[52] U.S. Cl. **623/1; 623/12**[58] Field of Search **623/1, 11, 12; 606/108, 191, 194, 195, 198****[56] References Cited****U.S. PATENT DOCUMENTS**

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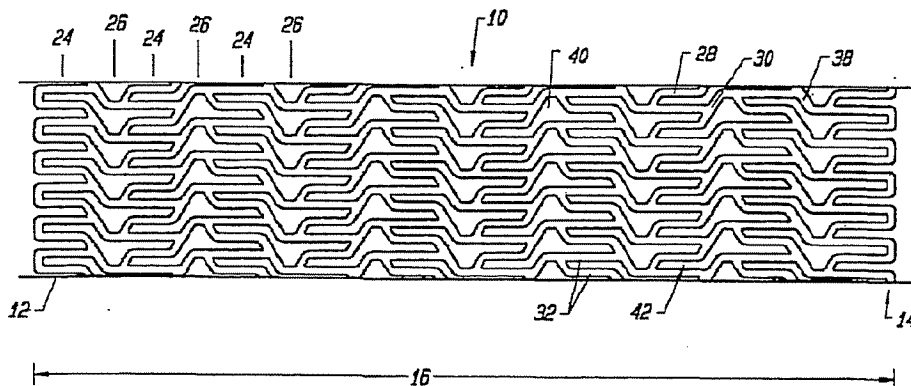
Primary Examiner—David H. Wilke

Assistant Examiner—Tram A. Nguyen

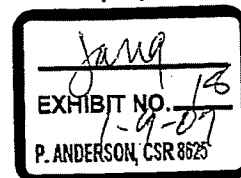
Attorney, Agent, or Firm—Wilson Sonsini Goodrich & Rosati

[57] ABSTRACT

A stent in a non-expanded state has a first expansion strut pair consisting of a first expansion strut positioned adjacent to a second expansion strut and a joining strut which couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column. A second expansion strut pair consists of a first expansion strut positioned adjacent to a second expansion strut and a joining strut couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column. A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section is coupled to the proximal end of the second expansion strut pair of the second expansion column. A plurality of the first connecting struts form a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.

85 Claims, 27 Drawing Sheets

41 pgs.



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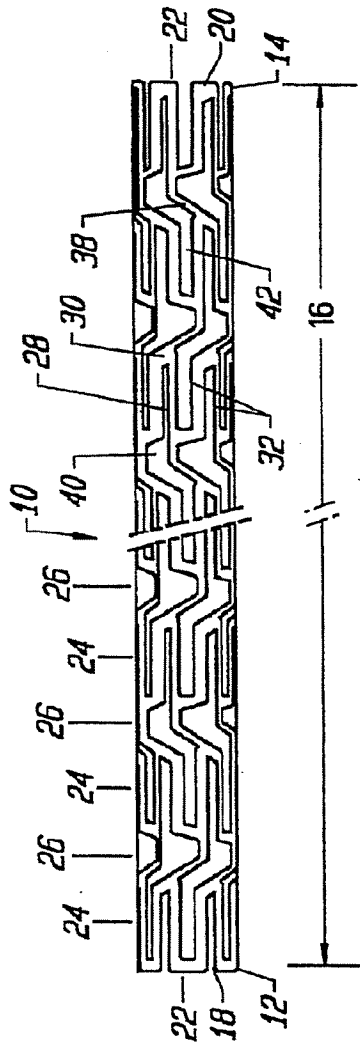


FIG. 1A

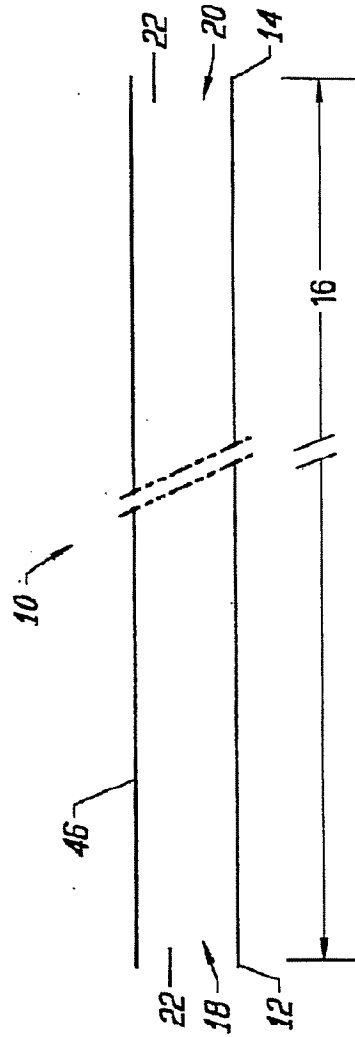


FIG. 1B

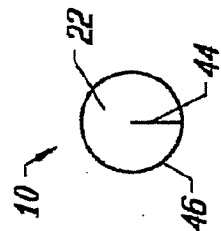


FIG. 1C

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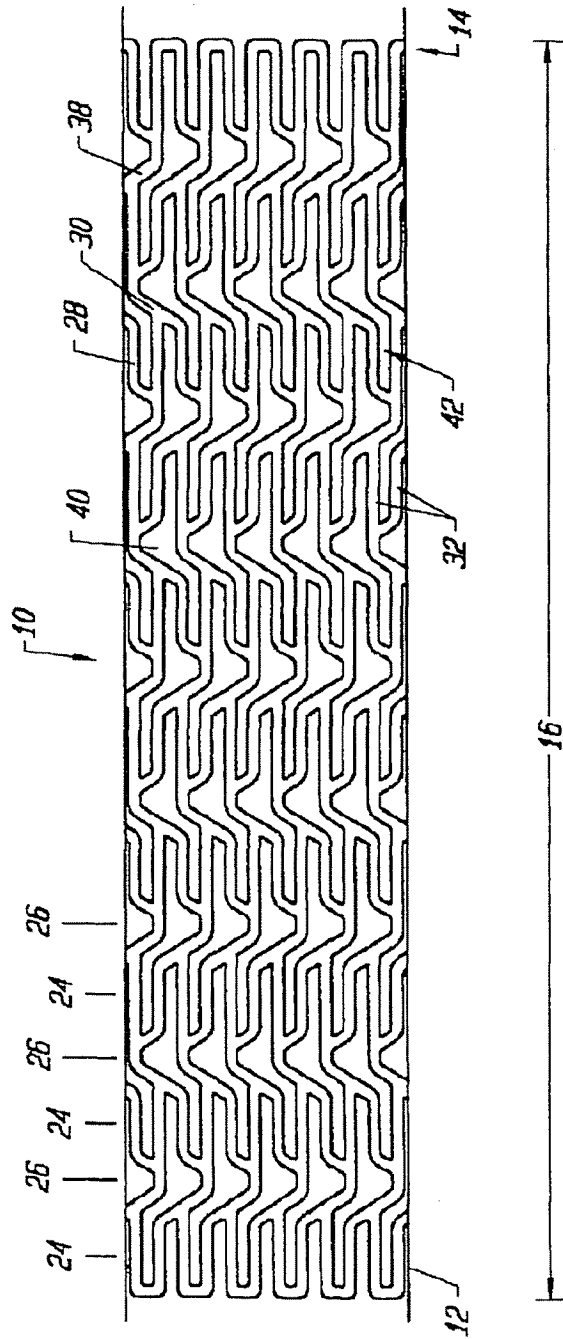


FIG. 2A

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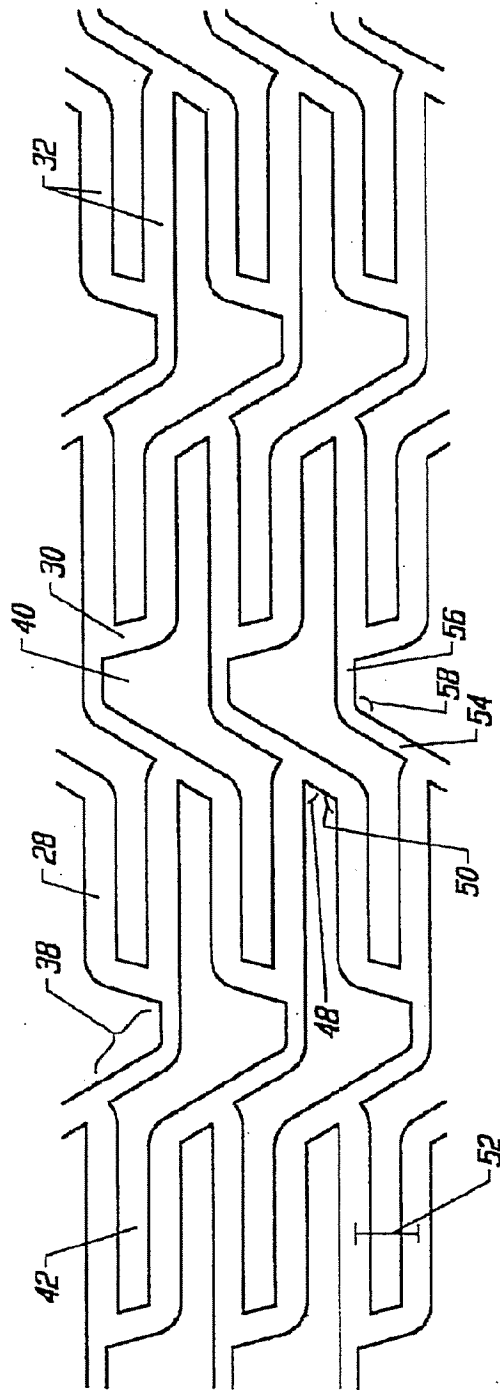


FIG. 2B

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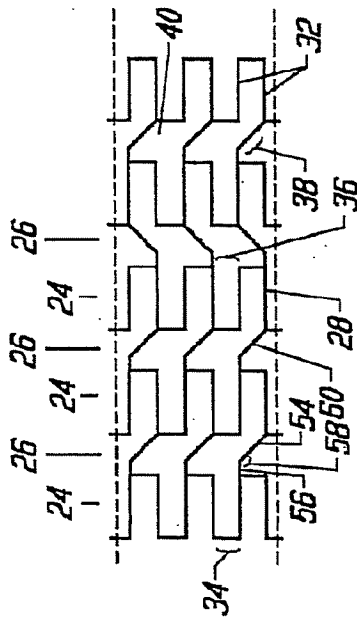


FIG. 3A

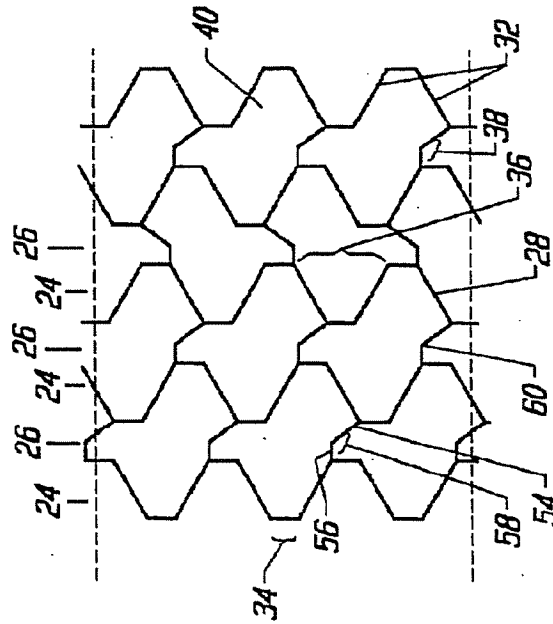


FIG. 3B

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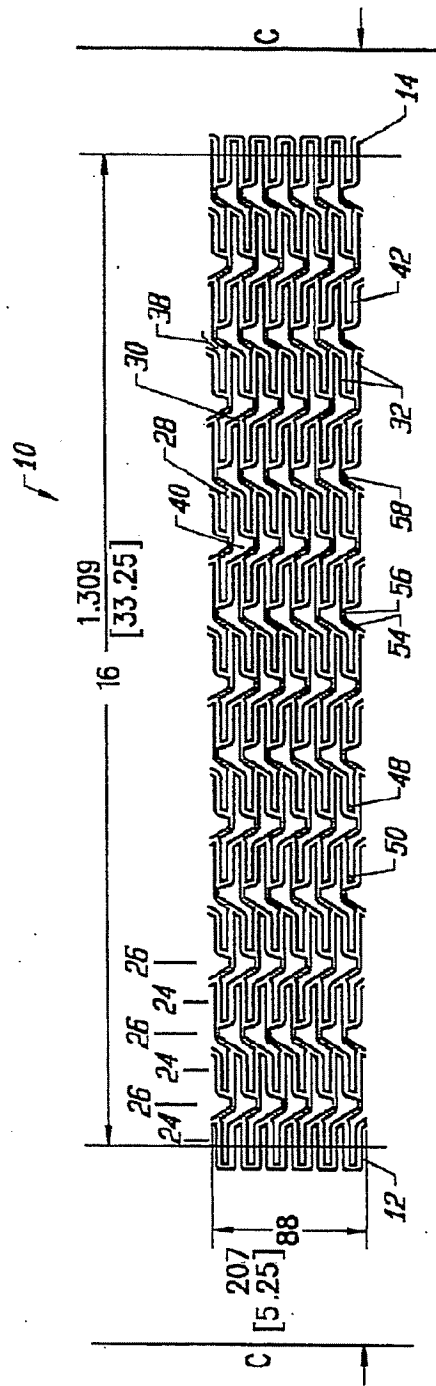


FIG. 4A

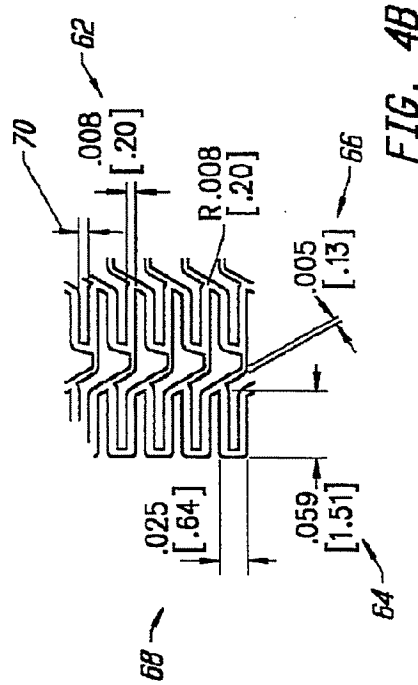


FIG. 4B

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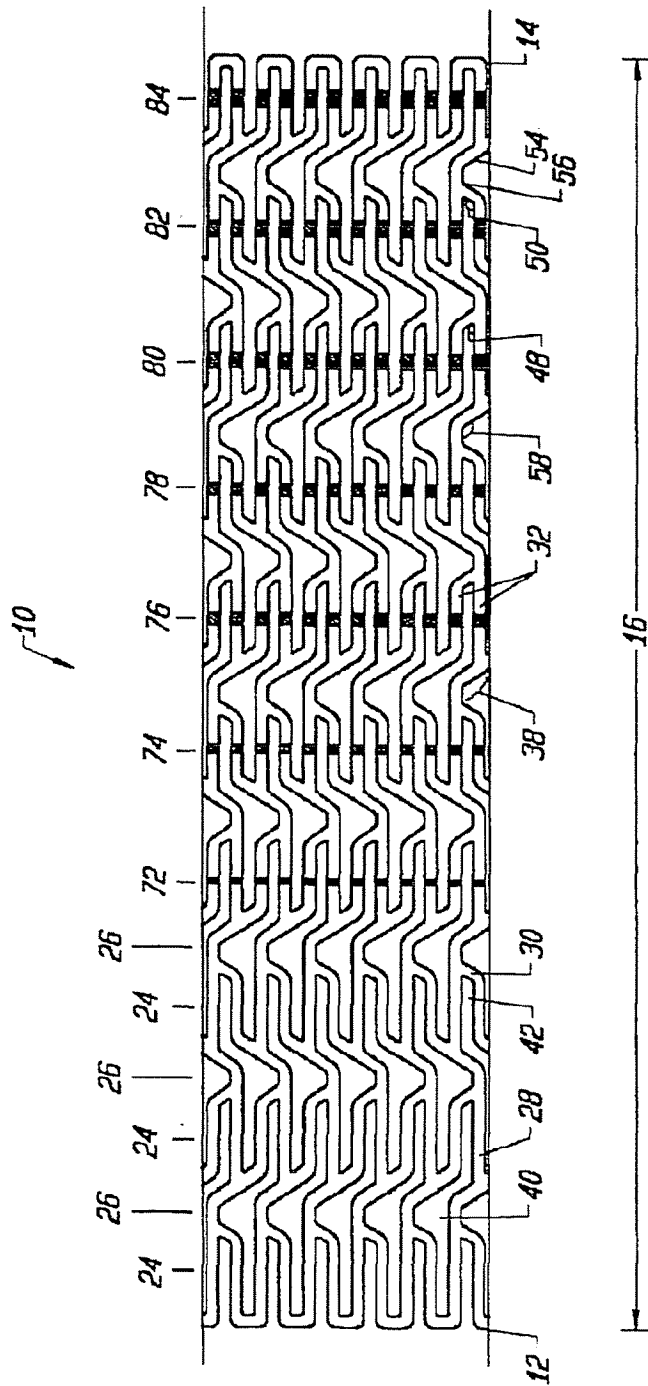


FIG. 5

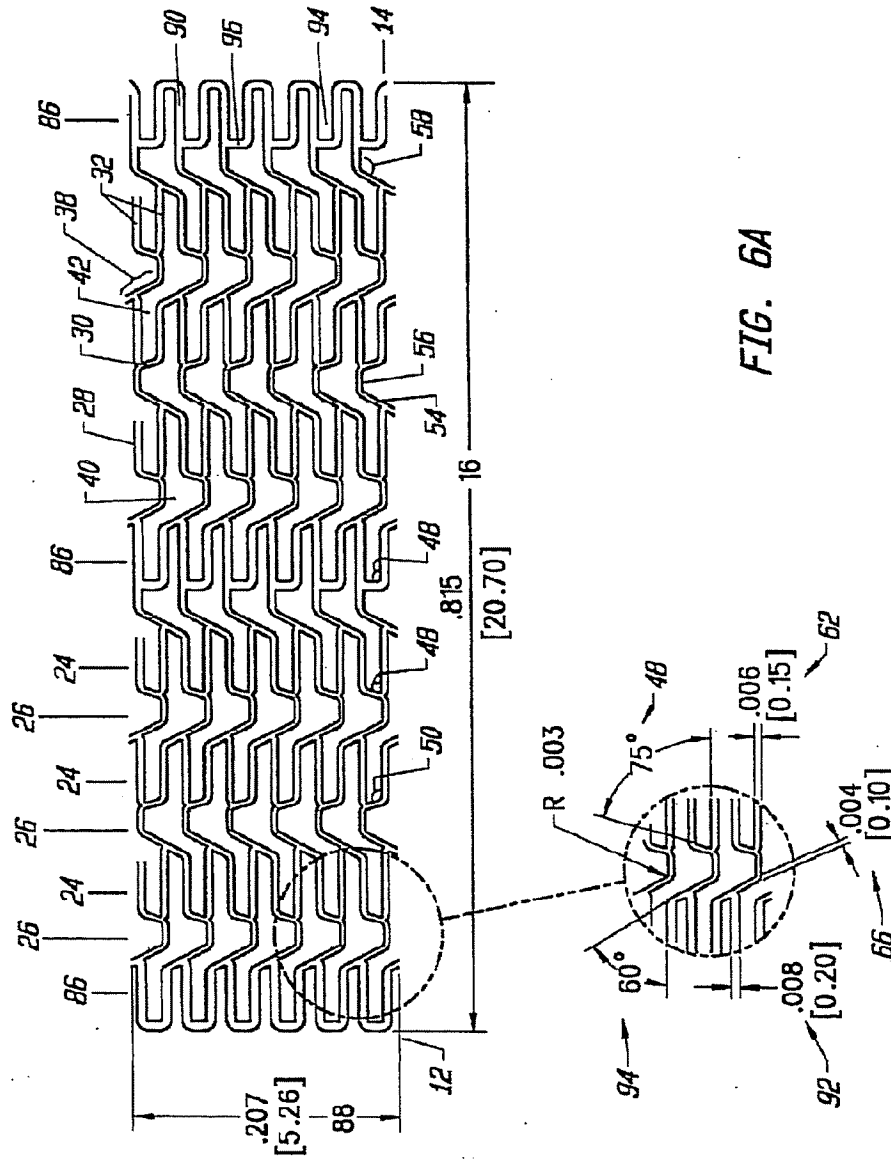
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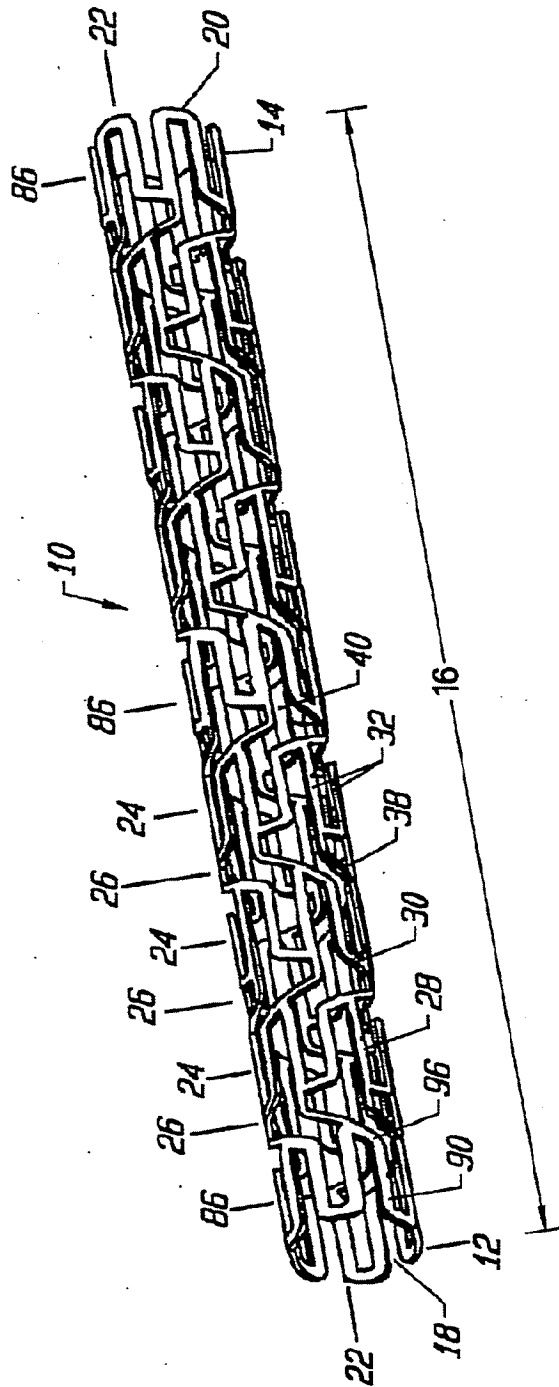


FIG. 6B

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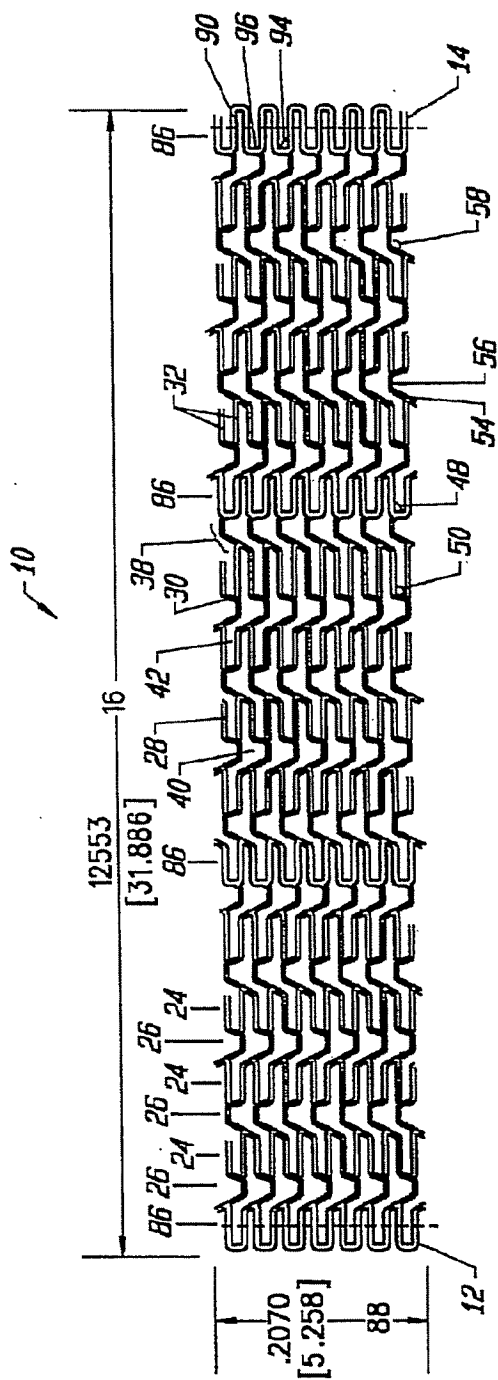


FIG. 7A

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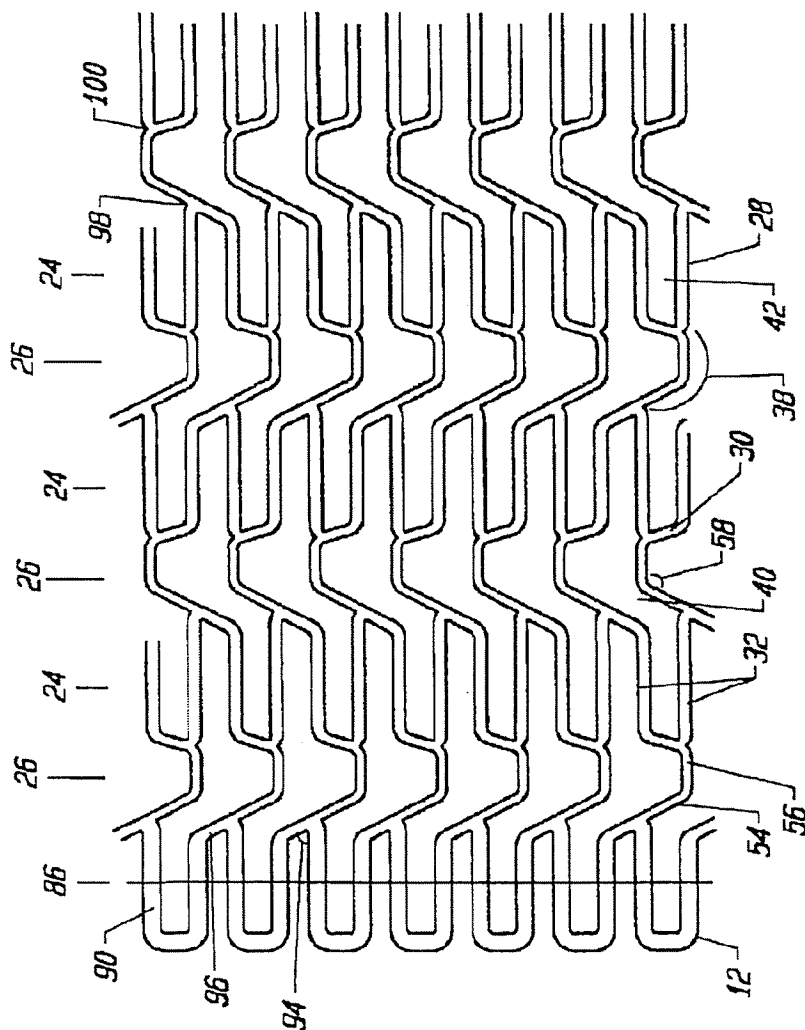


FIG. 7B

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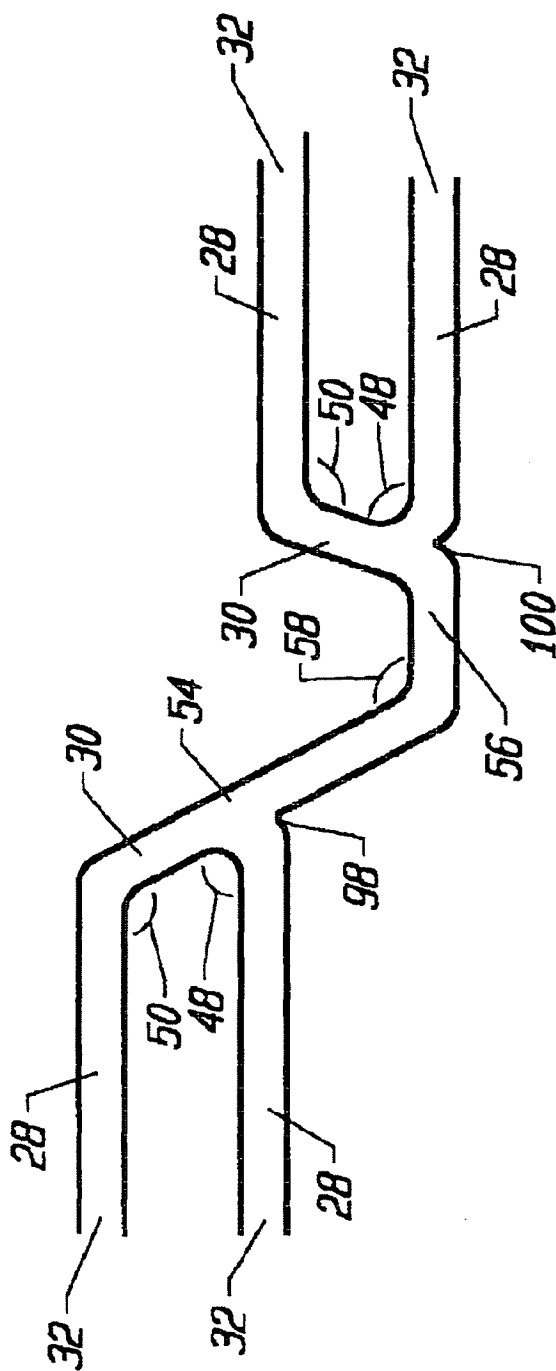


FIG. 7C

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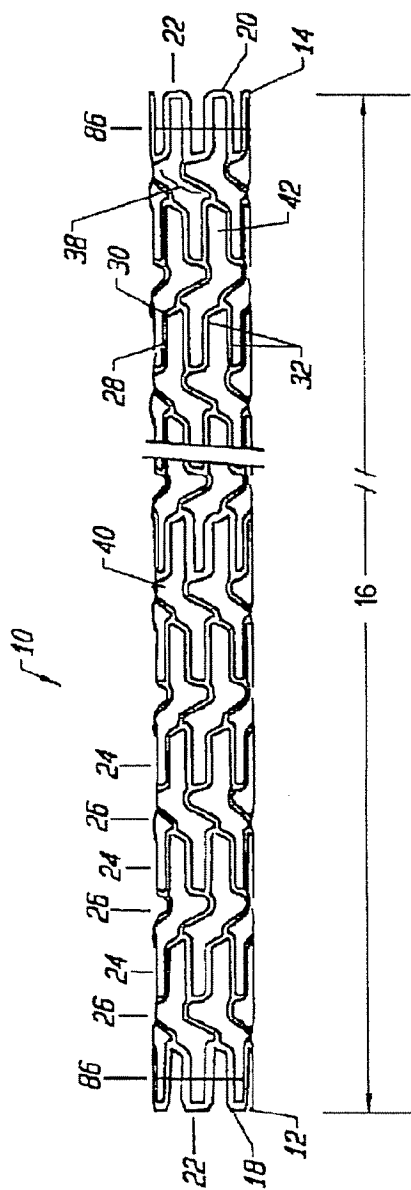


FIG. 8A

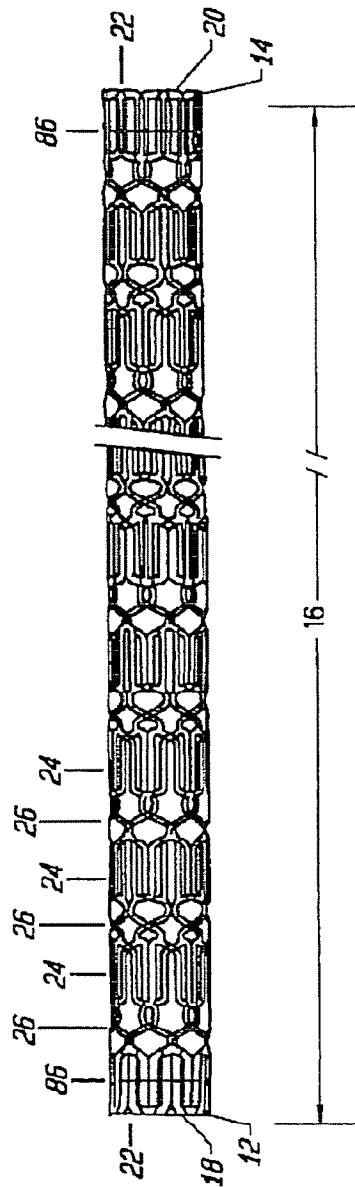


FIG. 8B

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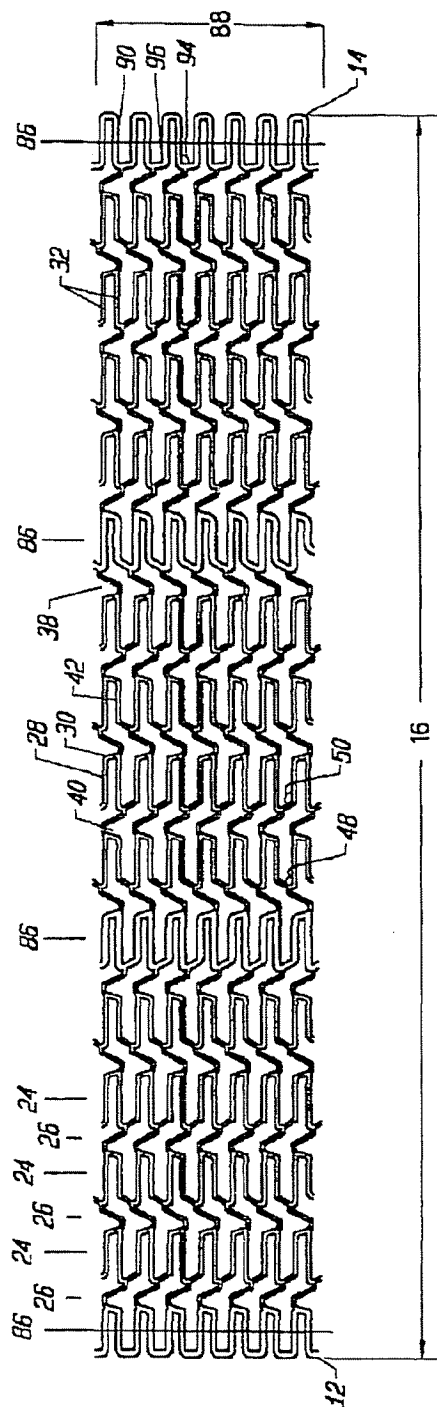


FIG. 8C

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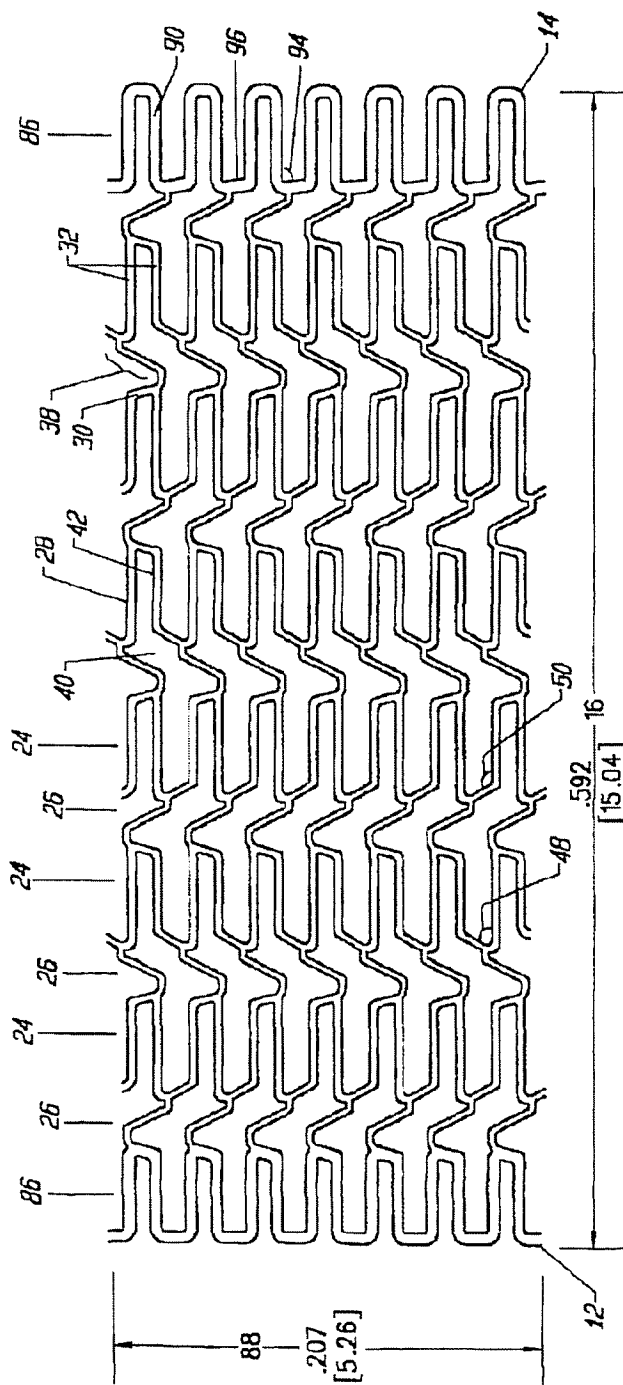


FIG. 80

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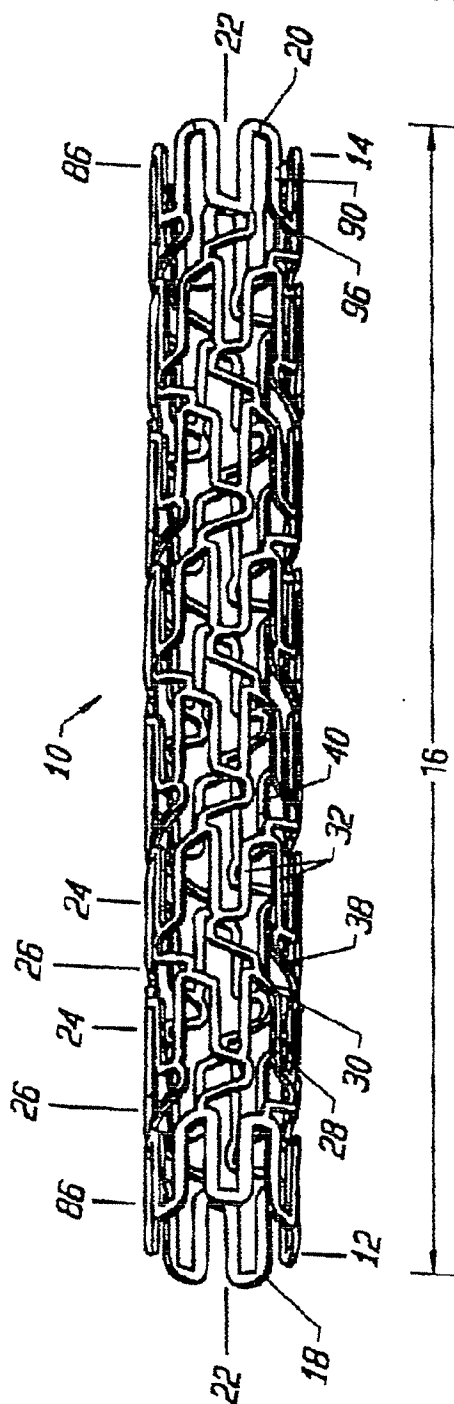
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FIG. 8E



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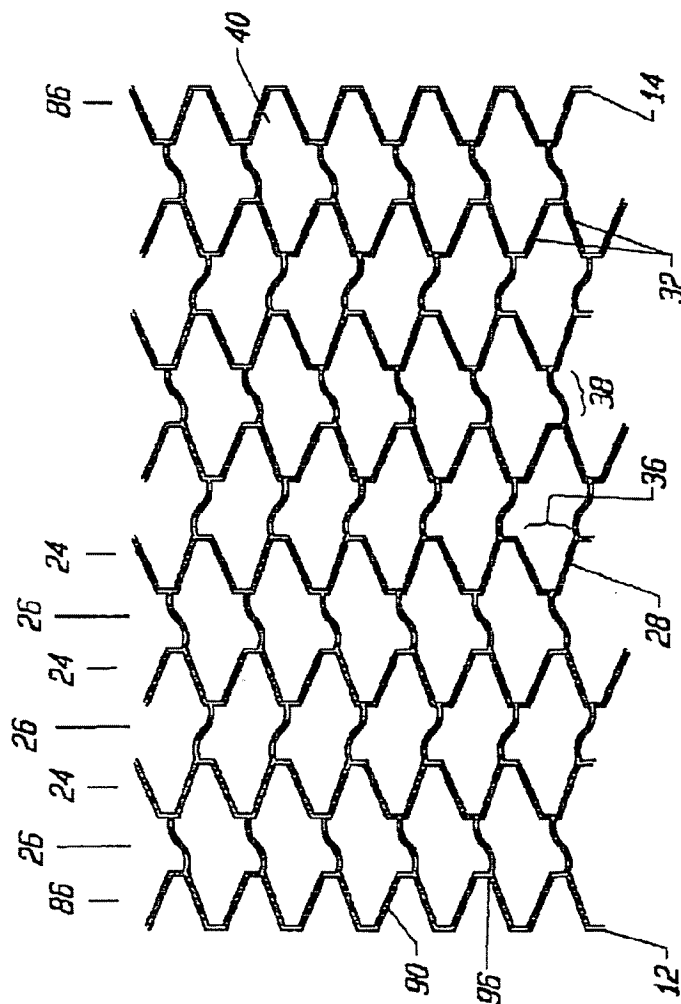


FIG. 8F

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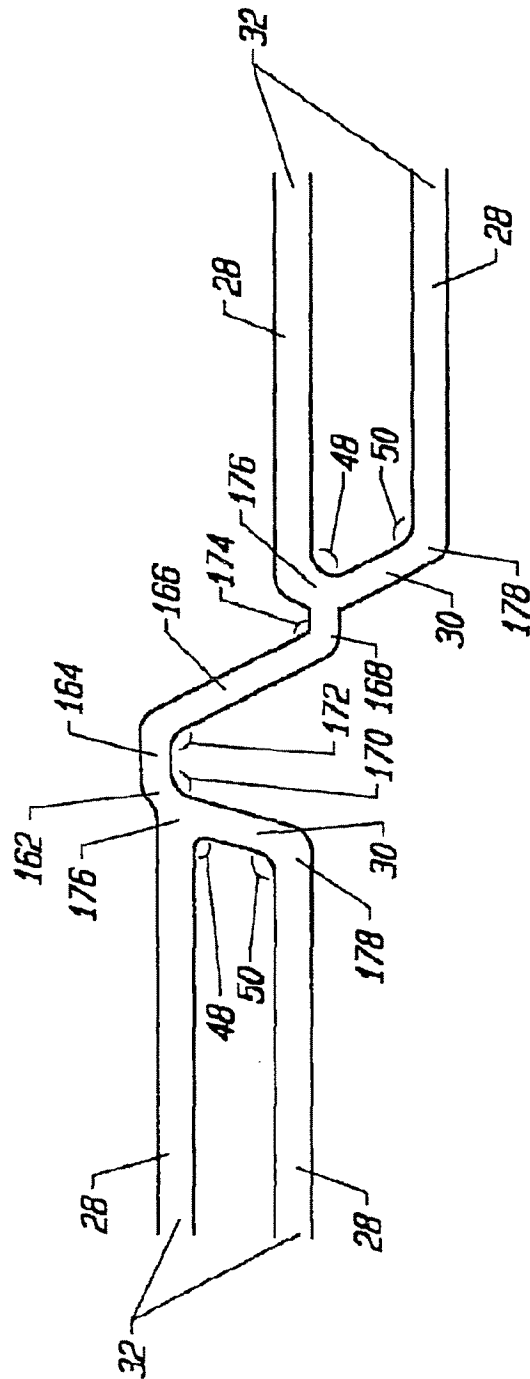


FIG. 86

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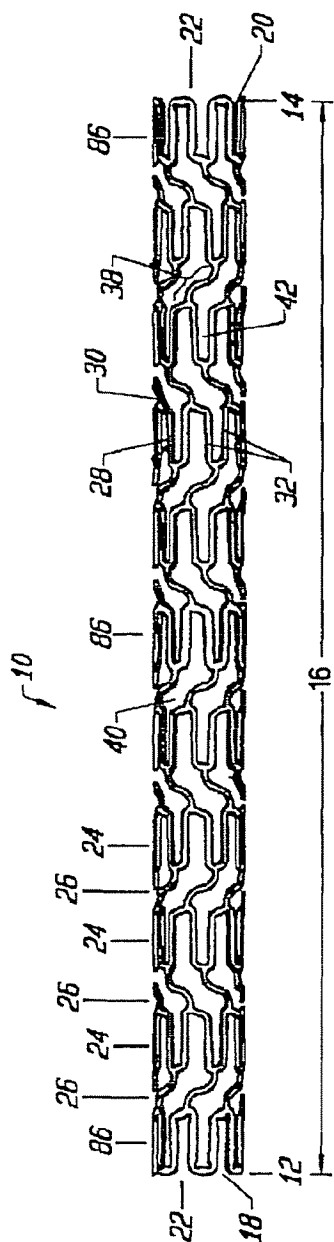


FIG. 9A

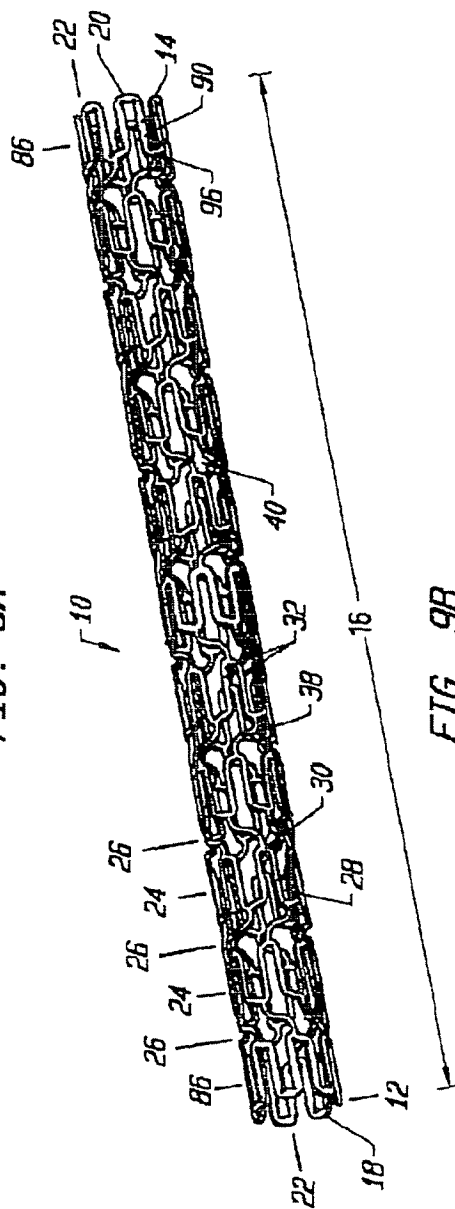


FIG. 9B

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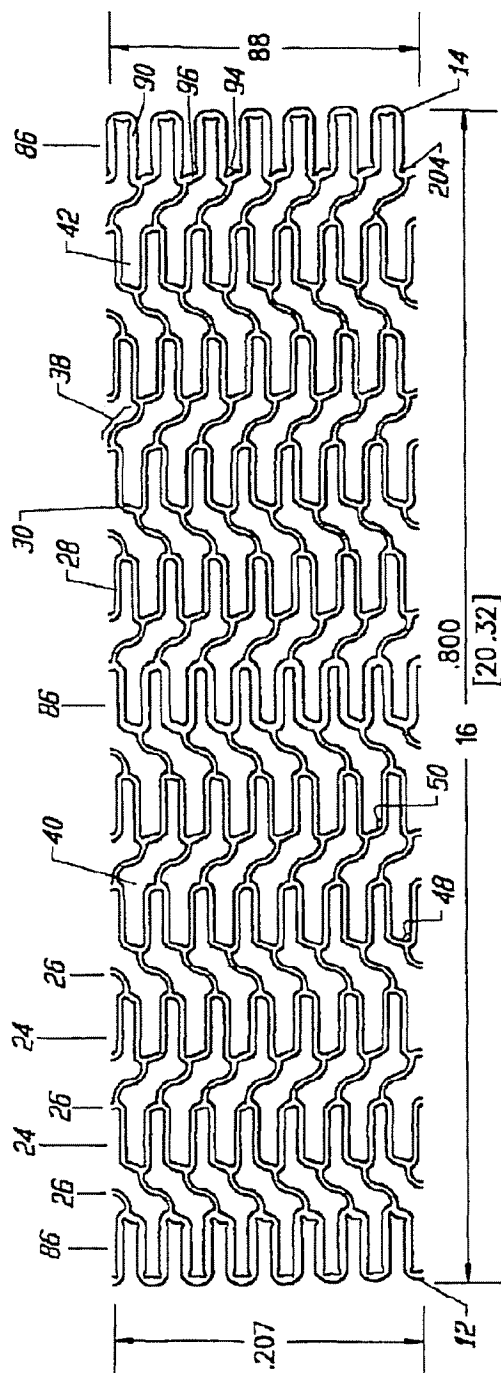


FIG. 9C

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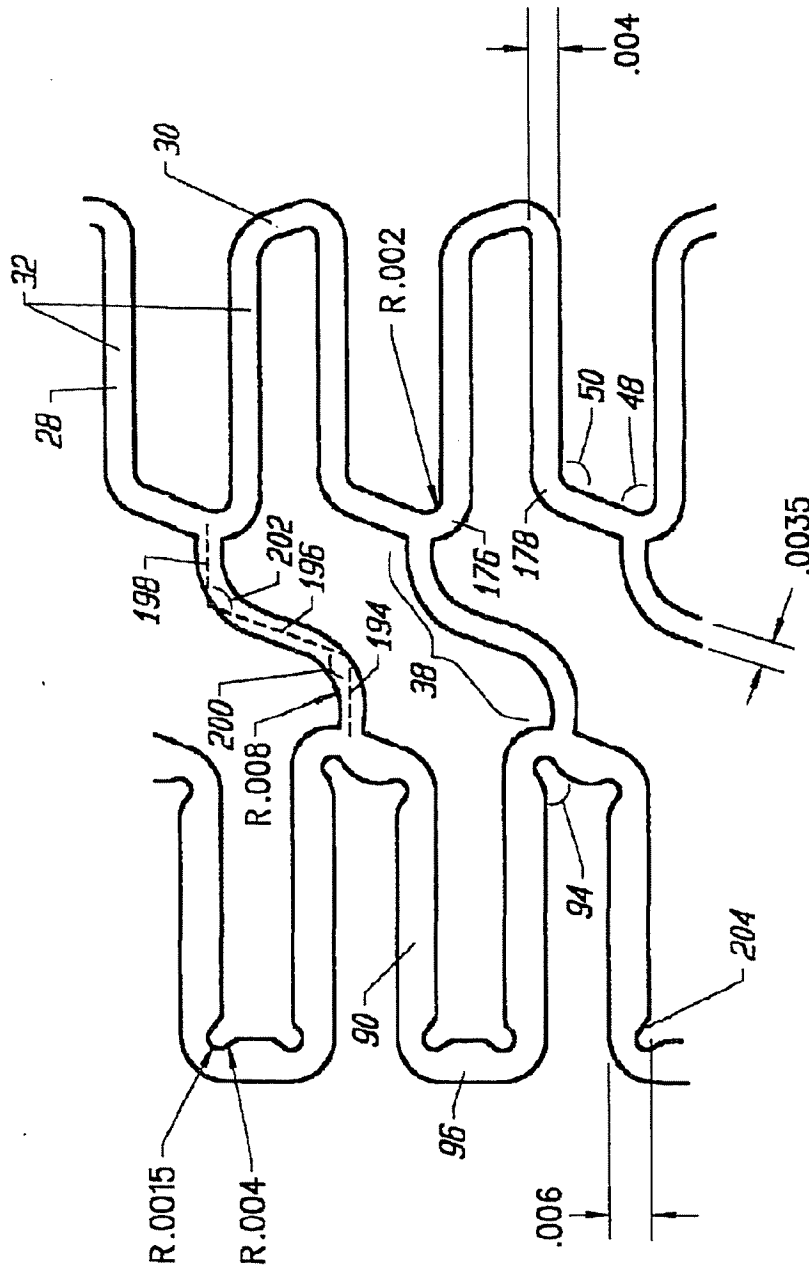


FIG. 9D

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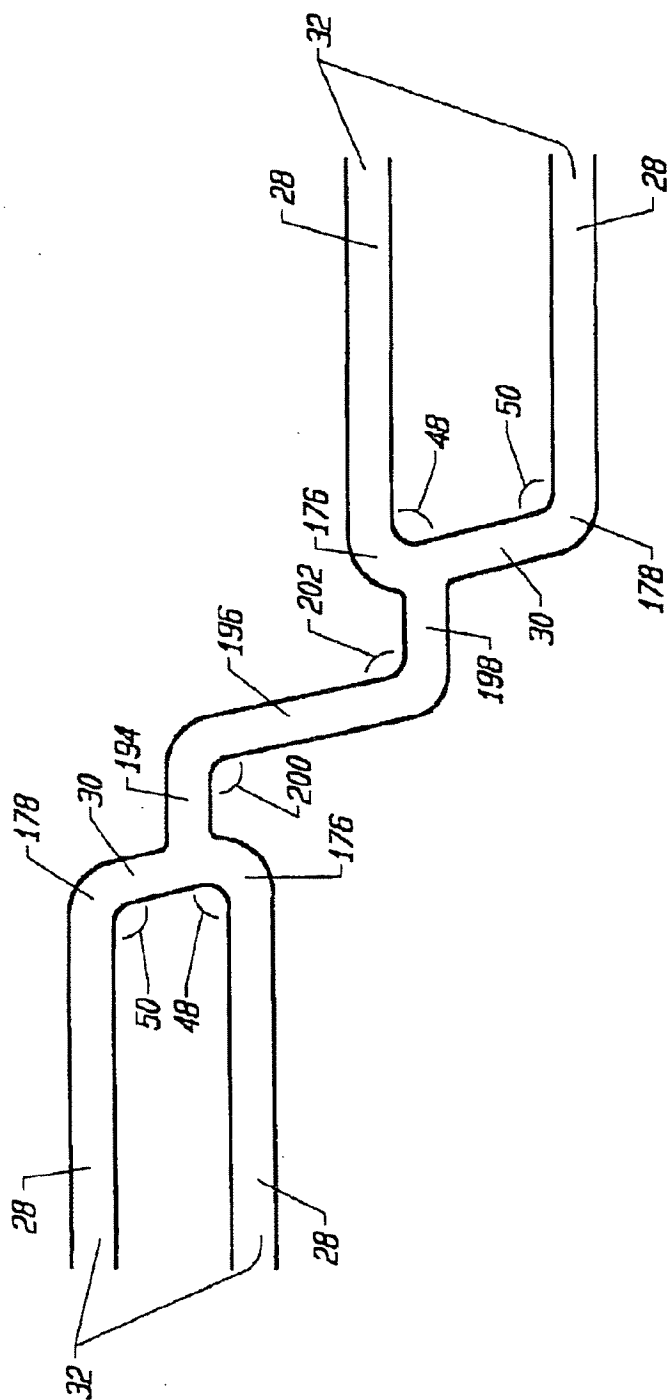


FIG. 9E

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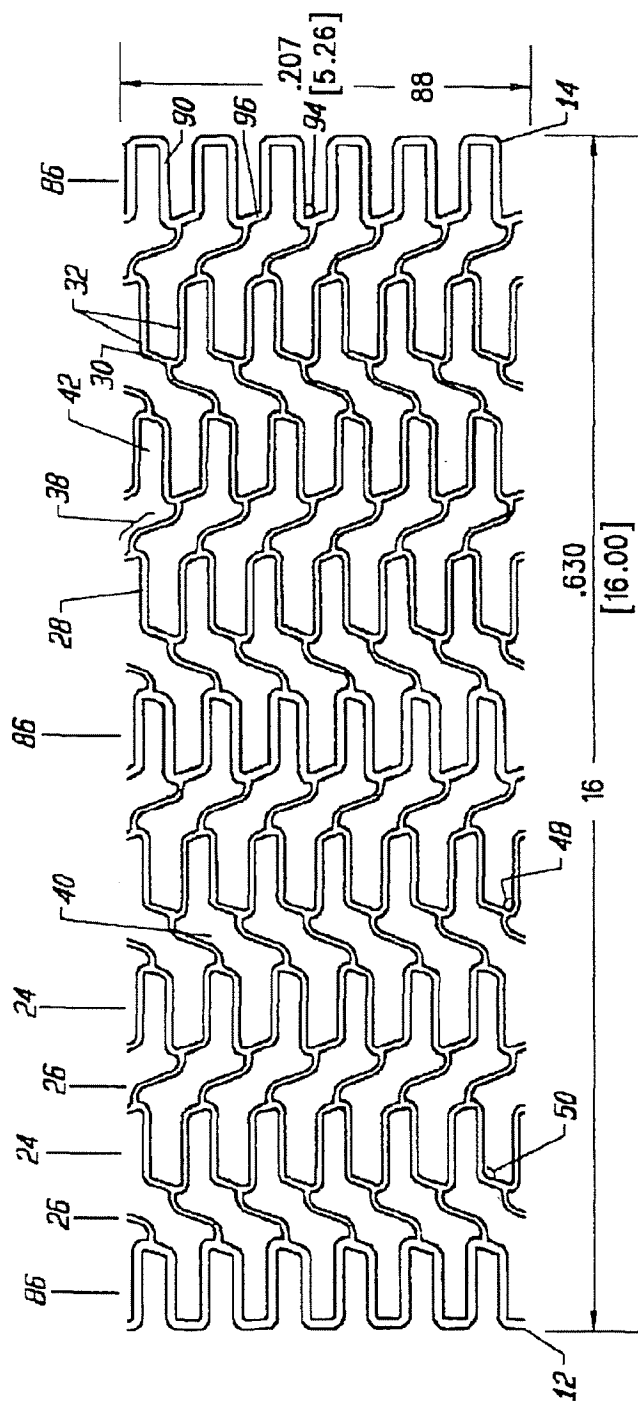


FIG. 9F

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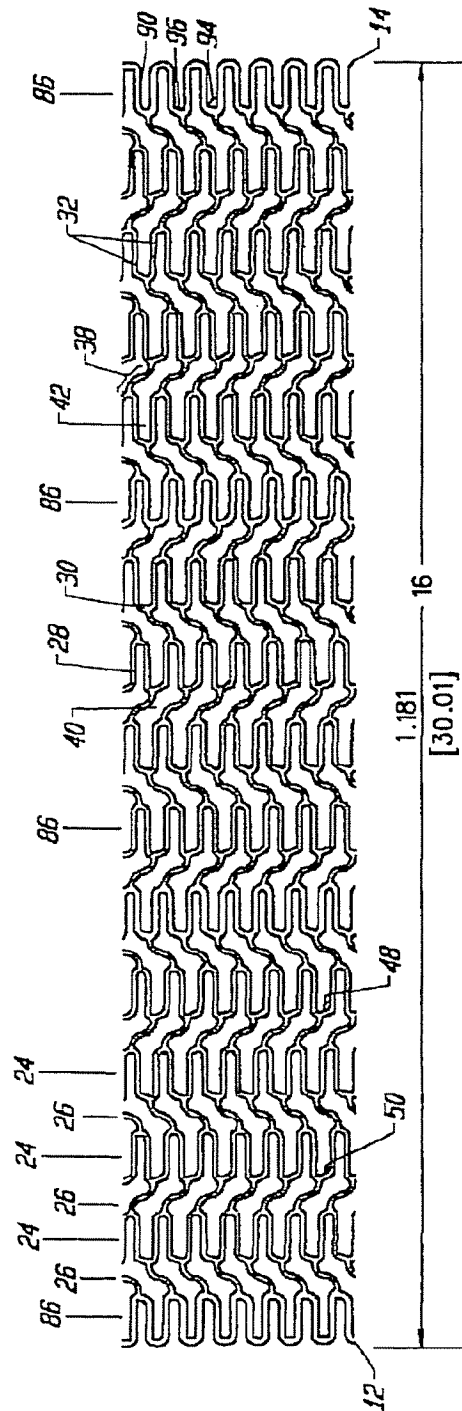


FIG. 96

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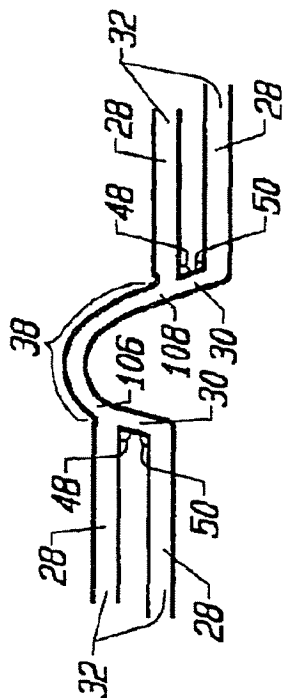


FIG. 10A

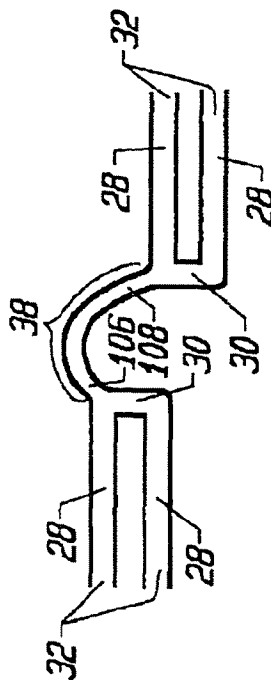


FIG. 10B

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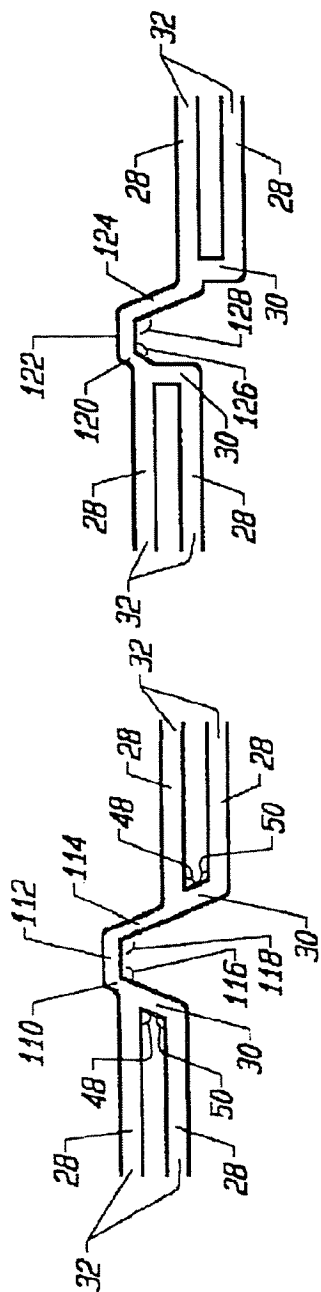


FIG. 10C

FIG. 10D

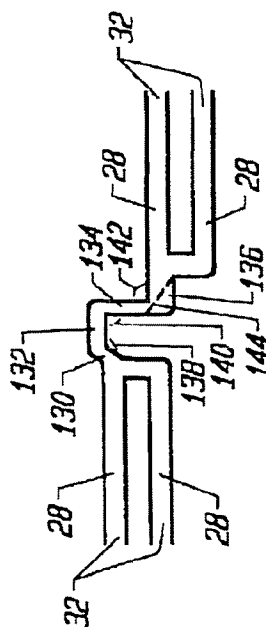


FIG. 10E

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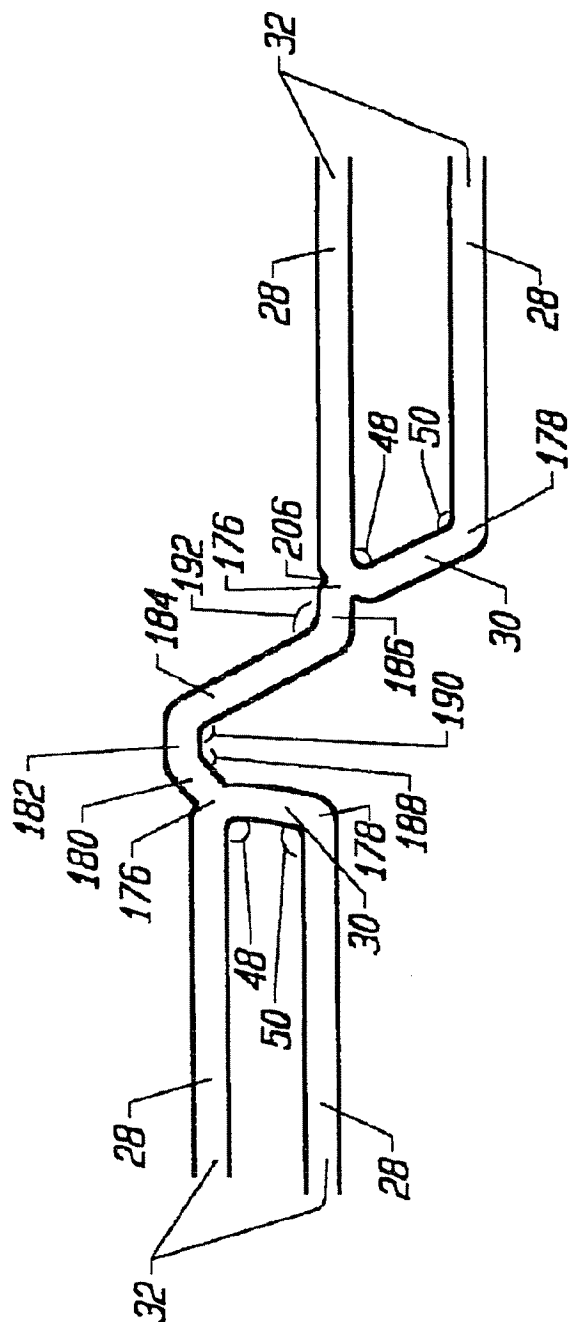


FIG. 10F

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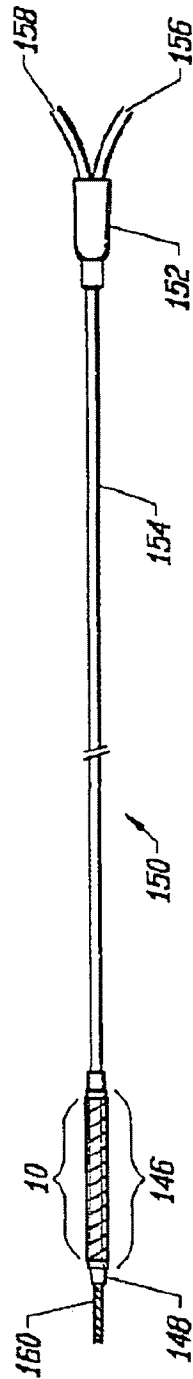


FIG. 11

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INTRAVASCULAR STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of Provisional Patent Application No. 60/017,484 filed Apr. 26, 1996, the disclosure of which is incorporated by reference. This application is a continuation in part of U.S. patent application Ser. No. 08/824,142, filed Mar. 25, 1997, entitled "Intravascular Stent", and a continuation in part of U.S. Pat. application Ser. No. 08/824,866, filed Mar. 25, 1997, entitled "Intravascular Stent", and a continuation in part of U.S. patent application Ser. No. 08/824,865, filed Mar. 25, 1997, entitled "Intravascular Stent" and is related to U.S. patent application Ser. No. 08/845,734, filed Apr. 25, 1997, entitled "Intravascular Stent" each having same named inventor G. David Jang and being incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to intravascular stents, and more particularly to an intravascular stent which provides easy introduction through tortuous sections of vessels.

2. Description of the Related Art

Angioplasty, either coronary or general vascular, has advanced to become the most effective means for revascularization of stenosed vessels. In the early 1980's, angioplasty first became available for clinical practice in the coronary artery, and has since proven an effective alternative to conventional bypass graft surgery. Balloon catheter dependent angioplasty has consistently proven to be the most reliable and practical interventional procedure. Other ancillary technologies such as laser based treatment, or directional or rotational atherectomy, have proven to be either of limited effectiveness or dependent on balloon angioplasty for completion of the intended procedure. Restenosis following balloon-based angioplasty is the most serious drawback and is especially prevalent in the coronary artery system.

Many regimens have been designed to combat restenosis, with limited success, including laser based treatment and directional or rotational atherectomy. Intravascular stenting, however, noticeably reduces the restenosis rate following angioplasty procedures. The procedure for intravascular stent placement typically involves pre-dilation of the target vessel using balloon angioplasty, followed by deployment of the stent, and expansion of the stent such that the dilated vessel walls are supported from the inside.

The intravascular stent functions as scaffolding for the lumen of a vessel. The scaffolding of the vessel walls by the stent serve to: (a) prevent elastic recoil of the dilated vessel wall, (b) eliminate residual stenosis of the vessel; a common occurrence in balloon angioplasty procedures, (c) maintain the diameter of the stented vessel segment slightly larger than the native unobstructed vessel segments proximal and distal the stented segment and (d) as indicated by the latest clinical data, lower the restenosis rate. Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels; treatments include drug therapy and other methods mentioned previously.

Another benefit of vessel stenting is the potential reduction of emergency bypass surgery arising from angioplasty procedures. Stenting has proven to be effective in some cases for treating impending closure of a vessel during

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angioplasty. Stenting can also control and stabilize an unstable local intimal tear of a vessel caused by normal conduct during an angioplasty procedure. In some cases, an incomplete or less than optimal dilation of a vessel lesion with balloon angioplasty can successfully be opened up with a stent implant.

Early in its development, the practice of stenting, especially in coronary arteries, had serious anticoagulation problems. However, anticoagulation techniques have since been developed and are becoming simpler and more effective. Better and easier to use regimens are continuously being introduced, including simple outpatient anticoagulation treatments, resulting in reduced hospital stays for stent patients.

An example of a conventional stent patent is U.S. Pat. No. 5,102,417 (hereinafter the Palmaz Patent). The stent described in the Palmaz Patent consists of a series of elongated tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members. The tubular members are connected by at least one flexible connector member.

The unexpanded tubular members of the Palmaz Patent are overly rigid so that practical application is limited to short lengths. Even with implementation of the multi-link design with flexible connector members connecting a series of tubular members, longer stents can not navigate tortuous blood vessels. Furthermore, the rigidity of the unexpanded stent increases the risk of damaging vessels during insertion. Foreshortening of the stent during insertion complicates accurate placement of the stent and reduces the area that can be covered by the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapered expanded stent, and no method of reinforcement of stent ends or other regions is provided for.

Another example of a conventional stent patent is WO 96/03092, the Brun patent. The stent described in the Brun patent is formed of a tube having a patterned shape, which has first and second meander patterns. The even and odd first meander patterns are 180 degrees out of phase, with the odd patterns occurring between every two even patterns. The second meander patterns run perpendicular to the first meander patterns, along the axis of the tube.

Adjacent first meander patterns are connected by second meander patterns to form a generally uniform distributed pattern. The symmetrical arrangement with first and second meander patterns having sharp right angled bends allows for catching and snagging on the vessel wall during delivery. Furthermore, the large convolutions in the second meander pattern are not fully straightened out during expansion reducing rigidity and structural strength of the expanded stent. There is, further, no method of programming the stent diameter along its longitudinal axis to achieve a tapering stent design, and no method of reinforcement of stent ends or other regions is provided for.

These and other conventional stent designs suffer in varying degrees from a variety of drawbacks including: (a) inability to negotiate bends in vessels due to columnar rigidity of the unexpanded stent; (b) lack of structural strength, axio-laterally, of the unexpanded stent; (c) significant foreshortening of the stent during expansion; (d) limited stent length; (e) constant expanded stent diameter; (f) poor crimping characteristics; and (g) rough surface modulation of the unexpanded stent.

There is a need for a stent with sufficient longitudinal flexibility in the unexpanded state to allow for navigation

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through tortuous vessels. There is a further need for a stent that is structurally strong in the unexpanded state such that risk of damage or distortion during delivery is minimal. A further need exists for a stent that maintains substantially the same longitudinal length during expansion to allow greater coverage at the target site and simplify proper placement of the stent. Yet a further need exists for a stent design with sufficient longitudinal flexibility that long stents of up to 100 mm can be safely delivered through tortuous vessels. There is a need for a stent that is configured to expand to variable diameters along its length, such that a taper can be achieved in the expanded stent to match the natural taper of the target vessel. A need exists for a stent which, (i) can be crimped tightly on the expansion balloon while maintaining a low profile and flexibility, (ii) has a smooth surface modulation when crimped over a delivery balloon, to prevent catching and snagging of the stent on the vessel wall during delivery or (iii) with reinforcement rings on the ends or middle or both to keep the ends of the stent securely positioned against the vessel walls of the target blood vessel.

SUMMARY OF THE INVENTION

Accordingly an object of the present invention is to provide a scaffold for an interior lumen of a vessel.

Another object of the invention is to provide a stent which prevents recoil of the vessel following angioplasty.

A further object of the invention is to provide a stent that maintains a larger vessel lumen compared to the results obtained only with balloon angioplasty.

Yet another object of the invention is to provide a stent that reduces foreshortening of a stent length when expanded.

Another object of the invention is to provide a stent with increased flexibility when delivered to a selected site in a vessel.

A further object of the invention is to provide a stent with a low profile when crimped over a delivery balloon of a stent assembly.

Yet a further object of the invention is to provide a stent with reduced tuliping of a stent frame.

Another object of the invention is to provide a chain mesh stent that reduces vessel "hang up" in a tortuous vessel or a vessel with curvature.

A further object of the invention is to provide a chain mesh stent that increases radial and axial-lateral strength of the expanded stent.

These and other objects of the invention are achieved in a stent in a non-expanded state. A first expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut and adjoining strut couples the first and second expansion struts at a distal end of the first expansion strut pair. A plurality of the first expansion strut pair form a first expansion column.

A second expansion strut pair includes a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair couples the first and second expansion struts at a proximal end of the second expansion strut pair. A plurality of the second expansion strut pair form a second expansion column.

A first connecting strut includes a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section. The first connecting strut proximal section is coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the

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second expansion column. A plurality of the first connecting struts forms a first connecting strut column that couples the first expansion column to the second expansion column. A length of the first connecting strut proximal section is equal to a length of the first connecting strut distal section, and a length of the first connecting strut intermediate section is greater than the length of the first connecting strut proximal and distal sections.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a side elevation view of the pre-expansion mode of an embodiment of the stent of the present invention;

FIG. 1B is a cross sectional view of an embodiment of the stent of the present invention;

FIG. 1C is a longitudinal cross sectional view of an embodiment of the stent of the present invention;

FIG. 2A is a scale drawing of the strut pattern of an embodiment of the stent of the present invention;

FIG. 2B is an expanded view of a section of the pattern of FIG. 2A;

FIG. 3A is a schematic illustration of a pre-expansion mode of an embodiment of the stent of the present invention;

FIG. 3B is a schematic illustration of the post-expansion mode of an embodiment of the stent of the present invention;

FIG. 4A is a scale drawing including dimensions of an embodiment of the stent of the present invention;

FIG. 4B is an enlarged section of the scale drawing of FIG. 4A;

FIG. 5 is a scale drawing of an embodiment of the stent of the present invention with a tapered diameter in its post-expansion mode;

FIG. 6A is a scale drawing of an embodiment of the stent of the present invention with reinforcement expansion columns;

FIG. 6B is a perspective view of the embodiment of FIG. 6A;

FIG. 7A is a scale drawing of an embodiment of the stent of the present invention including relief notches at strut joints to increase flexibility of the joints;

FIG. 7B is an enlarged region of the embodiment of FIG. 7A;

FIG. 7C is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with the embodiment of FIG. 7A;

FIG. 8A is a side elevation view of an embodiment of the stent of the present invention;

FIG. 8B is a side elevation view of an embodiment of the stent of the present invention, shown as if the stent struts and space there between were transparent;

FIG. 8C is a scale drawing of an embodiment of the stent of the present invention;

FIG. 8D is a variation of the embodiment of the stent of FIG. 8C;

FIG. 8E is a perspective view of the embodiment of FIG. 8D;

FIG. 8F is a drawing illustrating the post-expansion mode of the stent of the embodiment of FIG. 8D of the present invention;

FIG. 8G is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with an embodiment of the present invention;

FIG. 9A is a side elevation view of an embodiment of the stent of the present invention;

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FIG. 9B is a perspective view of the embodiment of FIG. 9A;

FIG. 9C is a scale drawing of the embodiment of FIG. 9A;

FIG. 9D is an enlarged region of the drawing of FIG. 9C;

FIG. 9E is a scale drawing of an embodiment of the stent of the present invention;

FIG. 9F is a scale drawing of an embodiment of the stent of the present invention;

FIG. 9G is an enlarged view of a single connecting strut joining two expansion strut pairs in accordance with an embodiment of the present invention;

FIG. 10A is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10B is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10C is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10D is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10E is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention;

FIG. 10F is a drawing of an alternate geometry of connecting struts and joining struts in accord with the present invention; and

FIG. 11 is a delivery balloon catheter, illustrating a method of deliver of a stent in accord with the present invention.

DETAILED DESCRIPTION

A first embodiment of the present invention is shown in FIGS. 1A, 1B, 1C, 2A, and 2B. Referring to FIG. 1A, an elongate hollow tubular stent 10 in an unexpanded state is shown. A proximal end 12 and a distal end 14 define a longitudinal length 16 of stent 10. The longitudinal length 16 of the stent 10 can be as long as 100 mm or longer. A proximal opening 18 and a distal opening 20 connect to an inner lumen 22 of stent 10. Stent 10 can be a single piece, without any seams or welding joints or may include multiple pieces.

Stent 10 is constructed of two to fifty or more expansion columns or rings 24 connected together by interspersed connecting strut columns 26. The first column on the proximal end 12 and the last column on the distal end 14 of stent 10 are expansion columns 24.

Expansion columns 24 are formed from a series of expansion struts 28, and joining struts 30. Expansion struts 28 are thin elongate members arranged so that they extend at least in part in the direction of the longitudinal axis of stent 10. When an outward external force is applied to stent 10 from the inside by an expansion balloon or other means, expansion struts 28 are reoriented such that they extend in a more circumferential direction, i.e. along the surface of cylindrical stent 10 and perpendicular to its longitudinal axis. Reorientation of expansion struts 28 causes stent 10 to have an expanded circumference and diameter. In FIG. 1A, expansion struts 28 of unexpanded stent 10 are seen to extend substantially parallel to the longitudinal axis of stent 10.

Expansion struts 28 are joined together by joining struts 30 to form a plurality of expansion strut pairs 32. Expansion

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strut pairs have a closed end 34 and an open end 36. Additional joining struts 30 join together expansion struts 28 of adjacent expansion strut pairs 32, such that expansion struts 28 are joined alternately at their proximal and distal ends to adjacent expansion struts 28 to form expansion columns 24. Each expansion column 24 contains a plurality, typically eight to twenty, twenty to sixty, or larger of expansion struts 28. Expansion columns are preferably continuous unbroken ring structures extending around the circumference of the stent 10; however, broken structures in which individual struts or pieces of struts are removed from an otherwise continuous expansion column 24 can also be used.

Connecting struts 38 connect adjacent expansion columns 24 forming a series of interspersed connecting strut columns 26 each extending around the circumference of stent 10. Each connecting strut 38 joins a pair of expansion struts 28 in an expansion column 24 to an adjacent pair of expansion struts 28 in an adjacent expansion column 24. For stent 10 of FIG. 1A, the ratio of expansion struts 28 in an expansion column 24 to connecting struts 38 in a connecting strut column 26 is two to one; however, this ratio in general can be x to 1 where x is greater or less than two. Furthermore, since the stent 10 of FIG. 1A begins with an expansion column 24 on the proximal end 12 and ends with an expansion column 24 on the distal end 14, if there are n expansion columns 24 with m expansion struts 28 per column, there will be $m-1$ connecting strut columns 26, and $n(m-1)/2$ connecting struts 38.

The reduced number of connecting struts 38 in each connecting strut column 26, as compared to expansion struts 28 in each expansion column 24, allows stent 10 to be longitudinally flexibility. Longitudinal flexibility can be further increased by using a narrow width connecting strut, providing additional flexibility and suppleness to the stent as it is navigated around turns in a natural blood vessel.

At least a portion of the open spaces between struts in stent 10 form asymmetrical cell spaces 40. A cell space or geometric cell is an empty region on the surface of stent 10, completely surrounded by one or a combination of stent struts, including expansion struts 28, connecting struts 38, or joining struts 30. Asymmetrical cell spaces 40 are cell spaces which have no geometrical symmetry i.e. no rotation, reflection, combination rotation and reflection or other symmetry. Asymmetrical cell spaces 40 have an asymmetrical geometric configuration.

Asymmetrical cell spaces 40 in FIG. 1A are surrounded by a first expansion strut pair 32 in a first expansion column 24, a first connecting strut 38, a second expansion strut pair 32 in an adjacent expansion column 24, a first joining strut 30, a second connecting strut 38, and a second joining strut 30. Furthermore, expansion strut pairs 32 of asymmetrical cell space 40 may be circumferentially offset i.e. have longitudinal axes that are not collinear and have their open ends 36 facing each other. The space between two expansion struts of an expansion strut pair 32 is known as a loop slot 42.

FIG. 1B shows inner lumen 22, radius 44 and stent wall 46 of stent 10. Stent wall 46 consists of stent struts including expansion struts 28, connecting struts 38 and joining struts 30.

FIG. 1C shows, proximal end 12, distal end 14, longitudinal length 16, inner lumen 22, and stent wall 46 of stent 10. Inner lumen 22 is surrounded by stent wall 46 which forms the cylindrical surface of stent 10.

Referring now to FIGS. 2A and 2B, joining struts 30 of stent 10 are seen to extend at an angle to the expansion struts

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28, forming a narrow angle 48 with one expansion strut 28 in an expansion strut pair 32 and a wide angle 50 with the other expansion strut 28 of an expansion strut pair 32. Narrow angle 48 is less than ninety degrees, while wide angle 50 is greater than ninety degrees. Joining struts 30 extend both longitudinally along the longitudinal axis of stent 10 and circumferentially, along the surface of the stent 10 perpendicular to its longitudinal axis.

Expansion strut spacing 52 between adjacent expansion struts 28 in a given expansion column 24 are uniform in stent 10 of FIGS. 2A and 2B; however, non-uniform spacings can also be used. Expansion strut spacings 52 can be varied, for example, spacings 52 between adjacent expansion struts 28 in an expansion column 24 can alternate between a narrow and a wide spacings. Additionally, spacings 52 in a single expansion column 24 can differ from other spacings 52 in other columns 24.

It is noted that varying expansion strut spacings 52 which form the loop slots 42 results in variable loop slot widths. Furthermore, the longitudinal axis of the loop slots 42 need not be collinear or even parallel with the longitudinal axis of loop slots 42 of an adjacent expansion column 24. FIGS. 2A and 2B show an arrangement of expansion struts 28 such that collinear, parallel adjacent loop slots 42 are formed, but non-collinear and non-parallel loop slots 42 can also be used.

Additionally the shape of loop slots 42 need not be the same among loop slots of a single or multiple expansion columns 24. The shape of loop slots 42 can be altered by changing the orientation or physical dimensions of the expansion struts 28 and/or joining struts 30 which connect expansion struts 28 of expansion strut pairs 32 defining the boundaries of loop slots 42.

Connecting struts 38 couple adjacent expansion columns 24, by connecting the distal end of an expansion strut pair in one expansion column 24 to the proximal end of an adjacent expansion strut pair 32 in a second expansion column 24. Connecting struts 38 of FIGS. 2A and 2B are formed from two linear sections, a first linear section 54 being joined at its distal end to a second linear section 56 at its proximal end to form a first slant angle 58.

The first linear section 54 of a connecting strut 38 is joined to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. First linear section 54 extends substantially collinear to joining strut 30 continuing the line of joining strut 30 into the space between expansion columns 24. The distal end of the first linear section 54 is joined to the proximal end of the second linear section 56 forming slant angle 58. Second linear section 56 extends substantially parallel to expansion struts 28 connecting at its distal end to joining strut 30 in an adjacent expansion column 24. The distal end of second linear section 56 attaches to expansion strut 28 at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. Further, joining strut 30 can have a second slant angle with a width that can be the same or different from the width of the first slant angle.

FIGS. 2A and 2B show connecting struts 38 and joining struts 30 slanted relative to the longitudinal axis of stent 10, with the circumferential direction of the slanted struts alternating from column to adjacent column. Circumferential direction refers to the handedness with which the slanted struts wind about the surface of the stent 10. The circumferential direction of the slant of connecting strut first linear sections 54 in a connecting strut column 26 is opposite the circumferential direction of the slant of connecting strut first

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linear sections 54 in an adjacent connecting strut column 26. Similarly, the circumferential direction of the slant of joining struts 30 in an expansion column 24 is opposite the circumferential direction of the slant of joining struts 30 in an adjacent expansion column 24. Alternating circumferential slant directions of connecting struts 38 and joining struts 30 prevents axial warping of stent 10 during deliver and expansion. Other non-alternating slant direction patterns can also be used for connecting struts 38 or joining struts 30 or both.

FIG. 3A and 3B show a schematic illustration of a stent design according to the present invention in an unexpanded and expanded state respectively. The design is depicted as a flat projection, as if stent 10 were cut lengthwise parallel to its longitudinal axis and flattened out. The connecting struts 38 consist of first and second linear sections 54 and 56 forming slant angle 58 at pivot point 60. An asymmetrical cell space 40 is formed by expansion strut pairs 32, connecting struts 38 and joining struts 30. Multiple interlocking asymmetrical cell spaces 40 make up the design pattern.

As the stent is expanded, see FIG. 3B, the expansion strut pairs 32 spread apart at their open ends 36, shortening the length of expansion struts 28 along the longitudinal axis of the cylindrical stent. The longitudinal shortening of expansion struts 28 during expansion is countered by the longitudinal lengthening of connecting struts 38. The widening of slant angle 58 during expansion straightens connecting struts 38 and lengthens the distance between the coupled expansion strut pairs 32. The widening of the slant angle of connecting struts 38 substantially compensates for the longitudinal shortening of expansion struts 28. Thus, the stent has substantially constant unexpanded and expanded longitudinal lengths.

When the stent is expanded, each expansion column 24 becomes circumferentially stretched, enlarging the space between struts. The interlinking of expansion columns 24 by connecting struts 38 that have been straightened through the expansion process gives the stent 10 a high radial support strength. The entire stent 10 when expanded is unitized into a continuous chain mesh of stretched expansion columns 24 and connecting strut columns 26 forming an asymmetrical interlocking cell geometry which resists collapse both axially and radially. When the stent is expanded it has increased rigidity and fatigue tolerance.

In addition, efficient bending and straightening of connecting struts 38 at pivot points 60 allows increased longitudinal flexibility of the stent. For the stent to bend longitudinally, at least some of connecting struts 38 are forced to bend in their tangent plane. The tangent plane of a specific connecting strut 38 refers to the plane substantially tangent to the cylindrical surface of the stent at that connecting strut 38. The width of connecting struts 38 can be twice as wide as a thickness. Preferably, a one-to-one ratio is preferred. However, pivot points 60 in connecting struts 38 provide connecting struts 38 a flexible joint about which to more easily bend increasing longitudinal flexibility of the stent.

Referring to FIGS. 4A and 4B, a variation of the first embodiment of stent 10 of the present invention is shown. In this variation, stent 10 has a length 16 of 33.25 mm and an uncrimped and unexpanded circumference 88 of 5.26 mm. Fifteen expansion columns 24 are interspersed with connecting strut columns 26. Each expansion column 24 consists of twelve expansion struts 28 joined alternately at their proximal and distal ends by joining struts 30 forming six expansion strut pairs 32. Expansion struts 28 are aligned parallel to the longitudinal axis of cylindrical stent 10.

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Joining struts 30 form a narrow angle 48 and a wide angle 50 with the respective expansion struts 28 of expansion strut pairs 32. Adjacent expansion columns 24 employ alternating circumferential slant directions of joining struts 30.

In this variation of the first embodiment, expansion strut width 62 is 0.20 mm, expansion strut length 64 is 1.51 mm, and connecting strut width 66 is 0.13 mm. Distance 68 from the outer edge of a first expansion strut 28 to the outer edge of a second adjacent expansion strut 28 in the same expansion column 24 is 0.64 mm, leaving a loop slot width 70 of 0.24 mm.

In this variation of the first embodiment, connecting struts 38 consist of a slanted first linear section 54 joined to a second linear section 56 at a slant angle 58. First linear section 54 is slightly longer than second linear section 56 and is attached at its proximal end to an expansion strut 28 in an expansion column 24. The attachment of the proximal end of first linear section 54 to expansion strut 28 is at the point where joining strut 30 makes narrow angle 48 with expansion strut 28. First linear section 54 extends substantially collinear to joining strut 30 attaching at its distal end to the proximal end of second linear section 56 to form slant angle 58. Second linear section 56 extends substantially collinear to expansion struts 28, attaching at its distal end to an expansion strut 28 in an adjacent expansion column 24. The attachment occurs at the point where expansion strut 28 forms narrow angle 48 with joining strut 30. Joining struts 30 and connecting strut first linear sections 54 slant in alternating circumferential directions from column to adjacent column.

The joining of connecting struts 38 and expansion struts 28 at the point where narrow angle 48 is formed aids smooth delivery of stent 10 by streamlining the surface of the unexpanded stent and minimizing possible catching points. Bare delivery of stent 10 to the target lesion in a vessel will thus result in minimal snagging or catching as it is navigated through turns and curvatures in the vessel. Stent 10 behaves like a flexible, tubular sled as it is moved forward or backward in the vessel or the delivery catheter, sliding through tortuous vessels and over irregular bumps caused by atherosclerotic plaques inside the vessel lumen.

When fully expanded Stent 10 of FIGS. 4A and 4B has an internal diameter of up to 5.0 mm, while maintaining an acceptable radial strength and fatigue tolerance. The crimped stent outer diameter can be as small as 1.0 mm or less depending on the condition of the underlying delivery balloon profile; A small crimped outer diameter is especially important if stent delivery is to be attempted without predilation of the target site. When the stent is optimally crimped over the delivery balloon, the surface of the crimped stent is smooth allowing for no snagging of the stent struts during either forward or backward movement through a vessel.

FIG. 5 shows a second embodiment of the present invention in which the stent 10 in its expanded form has a gradual taper from proximal end 12 to distal end 14. The shaded segments 72, 74, 76, 78, 80, 82 and 84 of expansion struts 28 represent regions of expansion struts 28 to be removed. Removal of the shaded segments 72, 74, 76, 78, 80, 82 and 84 provides stent 10 with a gradual taper when expanded with distal end 14 having a smaller expanded diameter than proximal end 12. The degree of shortening of the expanded diameter of the stent 10 at a given expansion column 24 will be proportional to the length of the removed segment 72, 74, 76, 78, 80, 82, or 84 at that expansion column 24. In the expanded stent 10 the shortened expansion struts 28 will

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have a shortened component along the circumference of the stent resulting in a shortened circumference and diameter. The tapered diameter portion can be positioned anywhere along the length of stent 10, and the tapering can be made more or less gradual by removing appropriately larger or smaller portions of the expansion struts 28 in a given expansion column 24.

Tapering is especially important in long stents, longer than 12 mm, since tapering of blood vessels is more pronounced over longer lengths. A long stent with a uniform stent diameter can only be matched to the target vessel diameter over a short region. If the proximal vessel size is matched with the stent diameter, the expanded distal end of the stent will be too large for the natural vessel and may cause an intimal dissection of the distal vessel by stent expansion. On the other hand, if the distal vessel size is matched with the stent diameter, the proximal end of the expanded stent will be too small to set inside the vessel lumen. It is therefore desirable to have a stent with a tapered expanded diameter.

Another way to achieve a tapered expanded stent is to change the stiffness of the stent struts, expansion struts, connecting struts or joining struts such that the stiffness of the struts varies along the length of the stent. The stiffness of the struts can be changed by altering length, width or thickness, adding additional stiffening material, using a chemical or mechanical means to alter the physical properties of the stent material, or applying one or a series of elastic elements about the stent.

Along with the use of a tapered diameter stent, a matching tapered balloon catheter would ideally be made for delivery and deployment of the tapered diameter stent. The method of using a tapered matching balloon catheter with a tapered diameter stent is within the scope of the present invention.

Using a tapered balloon to expand a non-tapered stent will also achieve a tapered expanded stent; however, since no metal is removed from the stent, the stent is tapered as a result of incomplete expansion. The stent will therefore have increased metal fraction at the tapered end resulting in increased risk of acute thrombosis. Metal fraction is the proportion of the surface of the expanded stent covered by the stent strut material. Shortening the expansion struts as shown in FIG. 5 allows for a tapered expanded stent with substantially constant metal fraction along its length.

A third embodiment of the present invention shown in FIGS. 6A and 6B has multiple reinforcement expansion columns 86 placed along the length of the stent 10. The reinforcement columns 86 are placed along the stent length to provide additional localized radial strength and rigidity to stent 10. Additional strength and rigidity are especially important at the ends of the stent to prevent deformation of the stent both during delivery and after placement. During delivery the stent ends can catch on the vessel wall possibly deforming the unexpanded stent and altering its expansion characteristics. After the stent has been placed it is important that the stent ends are rigid so that they set firmly against the vessel wall; otherwise, during a subsequent catheter procedure, the catheter or guidewire can catch on the stent ends pulling the stent away from the vessel wall and possibly damaging and/or blocking the vessel.

The specific variation of the third embodiment of stent 10 depicted in FIGS. 6A and 6B has a length 16 of 20.70 mm and an uncrimped and unexpanded circumference 88 of 5.26 mm. The stent 10 consists of six expansion columns 24 and three reinforcement expansion columns 86, each consisting respectively of twelve expansion struts 28 or reinforcement

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expansion struts 90. The reinforcement expansion columns 86 are positioned one at either end, and one along the length of the stent 10.

The expansion strut width 62 is 0.15 mm, reinforcement expansion strut width 92 is 0.20 mm, and the connecting strut width 66 is 0.10 mm. The narrow angle 48 formed by joining strut 30 and expansion strut 28 is 75 degrees, and the narrow angle 94 formed by reinforcement joining strut 96 and reinforcement expansion strut 90 is 60 degrees.

Other arrangements of reinforcement expansion columns 86, such as providing reinforcement expansion columns 86 only on the ends of the stent, only on one end, or at multiple locations throughout the length of the stent can also be used and fall within the scope of the present invention. A taper can also be programmed into the reinforced stent 10 by shortening expansion struts 28 and reinforcement expansion struts 90 in appropriate expansion columns 24 and 86.

A fourth embodiment of the present invention, shown in the FIGS. 7A, 7B and 7C, is similar to the third embodiment but has the added feature of relief notches 98 and 100. A relief notch is a notch where metal has been removed from a strut, usually at a joint where multiple struts are connected. Relief notches increase flexibility of a strut or joint by creating a thinned, narrow region along the strut or joint. Relief notch 98 is formed at the joint formed between first linear section 54 of connecting strut 38 and expansion strut 28. Relief notch 100 is formed at the joint between second linear section 56 of connecting strut 38 and expansion strut 28. The positioning of the relief notches gives added flexibility to the unexpanded stent and prevents warping at the joints when the stent is expanded. This results in a smooth surface modulation to the expanded stent frame. Relief notches can be placed at other joints and can be included in any of the previously mentioned embodiments.

FIGS. 8A and 8B show a side elevation view of a variation of the fifth embodiment of the stent of the present invention. In this embodiment a four piece slanted connecting strut 38 is used to couple the corner of an expansion strut pair 32 in one expansion column 24 to the joining strut 30 of a circumferentially offset expansion strut pair 32 in an adjacent expansion column 24. The expansion struts 28, joining struts 30, expansion columns 24, reinforcement expansion struts 90, reinforcement joining struts 96, and reinforcement expansion columns 86 are substantially similar to the fourth embodiment of FIG. 6A. Connecting struts 38 in connecting strut columns 26, however, have an altered geometry and connectivity, described in more detail below.

FIG. 8A shows only the stent struts on the front half of the stent surface. The stent struts on the rear half of the stent surface are not shown. The stent appears as it would if the stent struts and space there between were opaque. FIG. 8B shows all stent struts from both the front and rear halves. The stent appears as it would if the stent struts and the space there between were transparent.

A first variation of a fifth embodiment of the present invention, shown in FIG. 8C consists of a stent 10 with twelve expansion columns 24, four reinforcement expansion columns 86, and fifteen connecting strut columns 26. In this variation, the stent 10 has a length 16 of 31.96 mm, and an unexpanded circumference 88 of 5.26 mm.

Connecting struts 38 shown in an enlarged view in FIG. 8G are made up of four linear sections, a proximal end section 162, first and second intermediate sections 164 and 166 respectively and a distal end section 168 forming three slant angles 170, 172 and 174. The proximal end of proximal section 162 is attached to a corner 176 of an expansion strut

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pair 32 of an expansion column 24. Corner 176 is formed where joining strut 30 makes narrow angle 48 with expansion strut 28. A second corner 178 of expansion strut 32 is formed where joining strut 30 makes wide angle 50 with expansion strut 28. Corners 176 and 178 can have an angular shape formed by joining linear expansion struts 28 and joining struts 30, or preferably corners 176 and 178 are rounded to remove sharp edges and provide increased flexibility. Additionally rounded corners provide stent 10 with greater expandability and reduce stress in the stent strut material at the corners in the expanded stent.

Proximal end section 162 of connecting strut 38 extends from corner 176 and is attached at its distal end to first intermediate section 164 forming slant angle 170. First intermediate section 164 extends from proximal end section 162 such that first intermediate section 164 is parallel to expansion struts 28 and is connected at its distal end to the proximal end of second intermediate section 166 forming slant angle 172.

Second intermediate section 166 extends in a slanted orientation relative to the longitudinal axis of stent 10, extending both longitudinally along and circumferentially about stent 10. Preferably, second intermediate section 166 is parallel to joining strut 30 of the circumferentially offset expansion strut pair 32 in adjacent expansion column 24.

Second intermediate section 166 attaches at its distal end to the proximal end of distal end section 168 forming slant angle 174. Distal end section 168 extends from second intermediate section 166 attaching at its distal end to joining strut 30 of circumferentially offset expansion strut pair 32 of adjacent expansion column 24. The attachment is at a point intermediate corners 176 and 178, where joining strut 30 forms narrow angle 48 and wide angle 50 respectively with expansion struts 28.

The connection point of distal end section 168 to joining strut 30 is closer to corner 176 than corner 178. Preferably the connection point is one to two or more expansion strut widths from corner 176. Offsetting the connection point of distal end section 168 to joining strut 30 from corner 176 to a point intermediate corner 176 and corner 178 reduces warping of the expanded stent 10, resulting in a smooth surface modulation and reduced risk of thrombosis. Additionally, this design provides a longer total straightened length of connecting strut 38, which further reduces foreshortening of stent 10 during expansion.

A second variation of a fifth embodiment of the present invention, shown in an unexpanded form in FIGS. 8D, 8E and in an expanded form in FIG. 8F consists of a stent 10 with six expansion columns 24, two reinforcement expansion columns 86, and seven connecting strut columns 26. In this variation, the stent 10 has a length 16 of 15.04 mm, and an unexpanded circumference 88 of 5.26 mm. The stent design 10 is substantially similar to the design of the first variation of the fifth embodiment of FIG. 8C with a reduced number of expansion columns, reinforcement expansion columns, and connecting strut columns.

FIG. 8F illustrates a portion of the expanded stent 10 of the second variation of the fifth embodiment. After expansion of stent 10 by balloon or other means, the expansion struts 28 are spread apart circumferentially, increasing the separation at the open end 36 of expansion strut pairs 32 resulting in an increase in the circumference of the stent 10. The spreading of the expansion struts 28 causes a longitudinal shortening of the expansion columns 24, which is compensated by a straightening of the connecting struts 38. During the expansion process, the slant angles 170, 172 and

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174 widen straightening the connection struts 38, and causing an increase in the separation distance between adjacent expansion columns 24. The asymmetrical interlocking cell geometry of the expanded stent is illustrated in FIG. 8F.

FIGS. 9A, 9B, 9C, 9D, 9E, 9F and 9G illustrate a sixth embodiment of the stent of the present invention. In this embodiment a three piece slanted connecting strut 38 is used to couple the joining strut 30 of an expansion strut pair 32 in one expansion column 24 to the joining strut 30 of a circumferentially offset expansion strut pair 32 in an adjacent expansion column 24. The joints between segments of connecting strut 38 are curved forming a smooth rounded shape. The expansion struts 28, joining struts 30, expansion columns 24, reinforcement expansion struts 90, reinforcement joining struts 96, and reinforcement expansion columns 86 are substantially similar to the fourth embodiment of FIG. 8A. Connecting struts 38 in connecting strut columns 26, however, have an altered geometry and connectivity, described in more detail below.

A first variation of a sixth embodiment of the present invention, shown in FIG. 9A, 9B and 9C consists of a stent 10 with eight expansion columns 24, three reinforcement expansion columns 86, and ten connecting strut columns 26. In this variation, the stent 10 has a length 16 of 20.32 mm.

Relief notches 204 are utilized at the joints between reinforcement expansion struts 90 and reinforcement joining struts 96 in the reinforcement expansion columns 86 at the stent proximal end 12 and distal end 14. Relief notches 204 reduce the width of the joints between reinforcement expansion struts 90 and reinforcement joining struts 96, which reduces stress in the metal at the joints during and after expansion of the stent. Relief notches 204 are particularly important at the stent ends since the stent ends are especially susceptible to warping during and after expansion. Preferably relief notches 204 reduce the joint widths, such that the joint widths are substantially the same as the thickness of stent wall 46 (see FIGS. 1B and 1C).

Connecting struts 38 shown in an enlarged view in FIG. 9D are made up of three linear sections, a proximal end section 194, an intermediate section 196 and a distal end section 198 forming two slant angles 200, 202. The connecting struts 38 have wide radii of curvature at the joints between connecting strut sections 194, 196 and 198. The shape of connecting strut 38 is thus curved or wavy rather than jagged and angular. The slant angles 200 and 202 are defined by linearly extrapolating proximal end section 194, intermediate section 196 and distal end section 198, as shown by the dotted lines in FIG. 9D.

FIG. 9E shows a variation of the connecting strut design of the sixth embodiment of the present invention. The connecting strut 38 of FIG. 9E has smaller radii of curvature at the joints between proximal end section 194, intermediate section 196 and distal end section 198. Connecting strut 38 of FIG. 9E is thus more jagged and angular than that of FIG. 9D.

Referring to the connecting struts 38 of FIG. 9D and 9E, the proximal end of proximal section 194 is attached to joining strut 30 of expansion strut pair 32 intermediate corners 176 and 178. Proximal end section 194 of connecting strut 38 extends from joining strut 30 and is attached at its distal end to intermediate section 196 forming slant angle 200. Intermediate section 196 extends from proximal end section 194 in a slanted orientation relative to the longitudinal axis of stent 10, extending both longitudinally along and circumferentially about stent 10. Intermediate section 196 is preferably parallel to joining struts 30 of coupled expansion strut pairs 32.

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Intermediate section 196 is connected at its distal end to the proximal end of distal end section 198 forming slant angle 202. Distal end section 198 extends from second intermediate section 196 attaching at its distal end to joining strut 30 of circumferentially offset expansion strut pair 32 of adjacent expansion column 24. The attachment is at a point intermediate corners 176 and 178, where joining strut 30 forms narrow angle 48 and wide angle 50 respectively with expansion struts 28.

The connection point of proximal end section 194 and distal end section 198 to joining struts 30 is closer to corner 176 than corner 178. Preferably the connection point is one to two or more expansion strut widths from corner 176. Offsetting the connection point of distal end section 198 to joining strut 30 from corner 176 to a point intermediate corner 176 and corner 178 reduces warping of the expanded stent 10, resulting in a smooth surface modulation and reduced risk of thrombosis. Additionally, this design provides a longer total straightened length of connecting strut 38, which further reduces foreshortening of stent 10 during expansion.

The connecting strut 38 of the sixth embodiment has one hundred and eighty degree rotational symmetry about its center. The symmetry of the connecting strut 38 does not, however, result in a symmetrical cell space as the width of loop slots 42 connected in each cell space are different. Adjacent loop slots 42 in each expansion column have alternating narrow and wide widths, preserving the asymmetry of the cell spaces. Introduction of one or many symmetrical cell spaces can be achieved in this design e.g. by providing uniform loop slot width to loop slots in adjacent expansion columns 24 contained in the same cell space. Additionally completely non-uniform cell space patterns utilizing symmetric or asymmetric cell spaces can be achieved e.g. by providing non-uniform variations in the widths of loop slots 42.

A second variation of a sixth embodiment of the present invention, shown in an unexpanded form in FIGS. 9F consists of a stent 10 with six expansion columns 24, three reinforcement expansion columns 86, and eight connecting strut columns 26. In this variation, the stent 10 has a length 16 of 16.00 mm, and an unexpanded circumference 88 of 5.26 mm. The stent design 10 is substantially similar to the design of the first variation of the sixth embodiment of FIGS. 9A, 9B and 9C with a reduced number of expansion columns 24 and connecting strut columns 26.

A third variation of a sixth embodiment of the present invention, shown in an unexpanded form in FIGS. 9F consists of a stent 10 with twelve expansion columns 24, four reinforcement expansion columns 86, and fifteen connecting strut columns 26. In this variation, the stent 10 has a length 16 of 30.01 mm, and an unexpanded circumference 88 of 5.25 mm. The stent design 10 is substantially similar to the design of the first variation of the sixth embodiment of FIGS. 9A, 9B and 9C with an increased number of expansion columns 24 reinforcement expansion columns 86 and connecting strut columns 26.

FIGS. 10A, 10B, 10C, 10D, 10E and 10F illustrate some examples of alternate connecting strut designs which can be used in any of the previously discussed embodiments. FIG. 10A shows a rounded loop connecting strut 38 which joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by adjoining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they

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connect. The rounded loop connecting strut 38 connects expansion struts 28 at the point where narrow angle 48 is formed between expansion struts 28 and joining struts 30. The slopes of the rounded connecting strut 38 at its proximal end 102 and distal end 104 substantially match the slopes of the joining struts 30 connecting the pairs of expansion struts 28. The rounded loop connecting strut 38 thus blends smoothly into the joining struts 30. Additionally the rounded loop connecting strut 38 has a first radius of curvature 106 and a second radius of curvature 108.

In the design of FIG. 10B a rounded loop connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are at right angles to the expansion struts 28 they connect. The rounded loop connecting strut 38 connects to expansion struts 28 at the same point as joining struts 30. The rounded connecting strut 38 has a first radius of curvature 106 and a second radius of curvature 108 such that it connects circumferentially offset expansion strut pairs 32.

In the design of FIG. 10C connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by adjoining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they connect. The connecting strut 38 connects expansion struts 28 at the point where narrow angle 48 is formed between expansion strut 28 and joining strut 30.

The connecting strut 38 is made up of three linear sections 110, 112, and 114 forming two slant angles 116 and 118. The proximal end of section 110 is attached to expansion strut 28 at the point where joining strut 30 forms narrow angle 48 with expansion strut 28. Section 110 extends substantially collinear to joining strut 30 and is attached at its distal end to intermediate section 112 forming slant angle 116. Intermediate section 112 extends at an angle to section 110 such that intermediate section 112 is substantially parallel to expansion struts 28 and is connected at its distal end to the proximal end of distal section 114 forming slant angle 118. Distal section 114 extends at an angle such that it is substantially collinear to joining strut 30 of the adjacent expansion strut pair 32. Distal section 114 attaches at its distal end to expansion strut 28 of the adjacent expansion strut pair 32, at the point where joining strut 30 forms narrow angle 48 with expansion strut 28.

In the design of FIGS. 10D and 10E a connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are at right angles to the expansion struts 28 they connect. The connecting strut 38 connects to expansion struts 28 at the same point as joining struts 30.

The connecting struts 38 of FIGS. 10D and 10E are made up of multiple connecting strut sections connected end to end to form a jagged connecting strut 38 with multiple slant angles, coupling expansion strut pair 32 to adjacent expansion strut pair 32. The connecting strut of FIG. 10D is made up of three connecting strut sections, a proximal section 120, an intermediate section 122 and a distal section 124 defining two slant angles 126 and 128, while the connecting strut of FIG. 10E consists of four connecting strut sections, a proximal section 130, intermediate sections 132 and 134, and a distal section 136 defining three slant angles 138, 140 and 142. In addition, connecting strut section 134 can be

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modified by replacing connecting strut section 136 by the dotted connecting strut section 144 to give another possible geometry of connecting struts 38.

In the design of FIGS. 10F connecting strut 38 joins two circumferentially offset expansion strut pairs 32 in adjacent expansion columns. Expansion struts 28 in each expansion strut pair 32 are joined by a joining strut 30. Joining struts 30 are slanted such as to form a narrow angle 48 and a wide angle 50 with the expansion struts 28 they connect.

Connecting strut 38 is made up of four linear sections, a proximal end section 180, first and second intermediate sections 182 and 184 respectively and a distal end section 186 forming three slant angles 188, 190 and 192. The proximal end of section 180 is attached to corner 176 at the point where joining strut 30 forms narrow angle 48 with expansion strut 28. Proximal end section 180 extends at an angle to joining strut 30 and is attached at its distal end to first intermediate section 182 forming slant angle 188. First intermediate section 182 extends at an angle to proximal end section 180 such that first intermediate section 182 is substantially parallel to expansion struts 28 and is connected at its distal end to the proximal end of second intermediate section 184 forming slant angle 190. Second intermediate section 184 is substantially longer than the first intermediate section 182. Second intermediate section 184 extends at an angle such that it is substantially collinear to joining strut 30 of the adjacent expansion strut pair 32. Second intermediate section 184 attaches at its distal end to the proximal end of distal end section 186 forming slant angle 192. Distal end section 186 extends in a slightly sloping orientation relative to expansion struts 28, attaching to corner 176 of expansion strut pair 32 where joining strut 30 forms narrow angle 48 with expansion strut 28. Relief notches 206 are formed at the joint between distal end segment 186 of connecting strut 38 and corner 176 of expansion strut pair 32 to increase flexibility of the unexpanded stent and prevent warping when the stent is expanded.

One skilled in the art will recognize that there are many possible arrangements of connecting struts and joining struts consistent with the present invention; the above examples are not intended to be an exhaustive list. In particular, it is noted that (a) connecting strut sections need not be linear but may contain one or many radii of curvature, (b) connecting strut sections may each have a different longitudinal axis, (c) the joint between connecting strut sections need not be jagged or sharp, but rather can be smooth containing one or multiple radii of curvature, and (d) relief notches may be present at any of the strut joints.

The stent of the present invention is ideally suited for application in coronary vessels although versatility in the stent design allows for applications in non-coronary vessels, the aorta, and nonvascular tubular body organs.

Typical coronary vascular stents have expanded diameters that range from 2.5 to 5.0 mm. However, a stent with high radial strength and fatigue tolerance that expands to a 5.0 mm diameter may have unacceptably high stent metal fraction when used in smaller diameter vessels. If the stent metal fraction is high, the chances of acute thrombosis and restenosis potential will increase. Even with the same metal fraction a smaller caliber vessel is more likely than a larger one to have a high rate of thrombosis. It is, therefore, preferred to have at least two different categories of stents for coronary application, for example, small vessels stents for use in vessels with diameters from 2.5 mm to 3.0 mm, and large vessel stents for use in vessels with diameters from 3.0 mm to 5.0 mm. Thus, both small vessels and large

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vessels when treated with the appropriate sized stent will contain stents of similar idealized metal fraction.

The stent of the present invention can be made using a CAM-driven laser cutting system to cut the stent pattern from a stainless steel tube. The rough-cut stent is preferably electro-polished to remove surface imperfections and sharp edges. Other methods of fabricating the stent can also be used such as EDM, photo-electric etching technology, or other methods. Any suitable material can be used for the stent including other metals and polymers so long as they provide the essential structural strength, flexibility, biocompatibility and expandability.

The stent is typically at least partially plated with a radiopaque metal, such as gold, platinum, tantalum or other suitable metal. It is preferred to plate only both ends of the stent by localized plating; however, the entire stent or other regions can also be plated. When plating both ends, one to three or more expansion columns on each end of the stent are plated to mark the ends of the stent so they can be identified under fluoroscopy during the stenting procedure. By plating the stent only at the ends, interference of the radiopaque plating material with performance characteristics or surface modulation of the stent frame is minimized. Additionally the amount of plating material required is reduced, lowering the material cost of the stent.

After plating, the stent is cleaned, typically with detergent, saline and ultrasonic means that are well-known in the art. The stents are then inspected for quality control, assembled with the delivery balloon catheter, and properly packaged, labeled, and sterilized.

Stent 10 can be marketed as stand alone or as a pre-mounted delivery balloon catheter assembly as shown in FIG. 11. Referring to FIG. 11, the stent 10 is crimped over a folded balloon 146 at the distal end 148 of a delivery balloon catheter assembly 150. The assembly 150 includes a proximal end adapter 152, a catheter shaft 154, a balloon channel 156, a guidewire channel 158, a balloon 146, and a guidewire 160. Balloon 146 can be tapered, curved, or both tapered and curved from a proximal end to a distal end in the expanded state. Additionally stent 10 can be non-tapered or tapered in the expanded state.

Typically the guidewire 160 is inserted into the vein or artery and advanced to the target site. The catheter shaft 154 is then forwarded over the guidewire 160 to position the stent 10 and balloon 146 into position at the target site. Once in position the balloon 146 is inflated through the balloon channel 156 to expand the stent 10 from a crimped to an expanded state. In the expanded state, the stent 10 provides the desired scaffolding support to the vessel. Once the stent 10 has been expanded, the balloon 146 is deflated and the catheter shaft 154, balloon 146, and guidewire 160 are withdrawn from the patient.

The stent of the present invention can be made as short as less than 10 mm in length or as long as 100 mm or more. If long stents are to be used, however, matching length or preferably slightly longer delivery catheter balloons will typically be needed to expand the stents into their deployed positions. Long stents, depending on the target vessel, may require curved long balloons, tapered long balloons or curved and tapered long balloons for deployment. Curved and/or tapered balloons which match the natural curve and taper of a blood vessel reduce stress on the blood vessel during and after stent deployment. This is especially important in many coronary applications which involve stenting in curved and tapered coronary vessels. The use of such curved and/or tapered balloons is within the scope of the present invention.

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The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

1. A stent in a non-expanded state, comprising:

a first expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the first expansion strut pair that couples the first and second expansion struts at a distal end of the first expansion strut pair, a plurality of the first expansion strut pair forming a first expansion column;

a second expansion strut pair including a first expansion strut positioned adjacent to a second expansion strut and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a plurality of the second expansion strut pair forming a second expansion column;

a first connecting strut including a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section, the first connecting strut proximal section being coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections, wherein the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

2. The stent of claim 1, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column are the same.

3. The stent of claim 1, wherein a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are different.

4. The stent of claim 1, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column, and a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are the same.

5. The stent of claim 1, wherein a spacing distance between the first expansion strut pair and an adjacent first expansion strut pair in the first expansion column, and a spacing distance between the second expansion strut pair and an adjacent second expansion strut pair in the second expansion column are different.

6. The stent of claim 1, wherein a first radius of curvature is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section.

7. The stent of claim 1, wherein a second radius of curvature is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

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8. The stent of claim 1, wherein a first radius of curvature is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section and a second radius of curvature is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

9. The stent of claim 1, wherein a first slant angle is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section.

10. The stent of claim 1, wherein a second slant angle is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

11. The stent of claim 1, wherein a first slant angle is formed where the first connecting strut proximal section is coupled to the first connecting strut intermediate section and a second slant angle is formed where the first connecting strut distal section is coupled to the first connecting strut intermediate section.

12. The stent of claim 1, wherein the stent further includes a radiopaque marker.

13. The stent of claim 1, wherein the stent includes an electroplated material for radiopaque observation under fluoroscopy.

14. The stent of claim 1, wherein a proximal end and a distal end of the stent are at least partially radiopaque electroplated.

15. The stent of claim 1, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1.

16. The stent of claim 1, wherein the stent includes m first and second expansion columns, n expansion struts per column and a $(m-1)/2$ connecting struts.

17. The stent of claim 1, wherein the first and second expansion columns are each unbroken, continuous structures.

18. The stent of claim 1, further comprising:

a reinforcement expansion column made of a plurality of reinforcement expansion struts, wherein each reinforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns.

19. The stent of claim 18, wherein the reinforcement expansion column includes a plurality of relief notches.

20. The stent of claim 1, wherein the stent has a proximal end with a first reinforcement expansion column and a distal end with a second reinforcement expansion column.

21. The stent of claim 20, wherein the first and second reinforcement expansion columns each include a plurality of relief notches.

22. The stent of claim 20, further comprising:

a third reinforcement expansion column intermediate the stent proximal end and the stent distal end.

23. A stent in a non-expanded state, comprising:

a first expansion column formed of a plurality of first expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion

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strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut;

a second expansion column formed of a plurality of second expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a first connecting strut column formed of a plurality of first connecting struts, each connecting strut of the first connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion

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strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

24. The stent of claim 23, wherein the stent includes a proximal expansion column, a distal expansion column, a plurality of connecting struts positioned between the proximal and distal expansion columns, and a plurality of expansion columns positioned between the proximal and distal expansion columns, each expansion column being made of a plurality of juxtapositioned proximal and distal looped slots.

25. The stent of claim 23, wherein the first expansion column, the second expansion column, and the first connecting strut column form a plurality of geometric cells.

26. The stent of claim 25, wherein at least a portion of the plurality are asymmetrical geometric cells.

27. The stent of claim 23, wherein the first expansion column, the second expansion column, and the first connecting strut column form a plurality of cells and at least a portion of the plurality of cells form non-uniform cell space patterns.

28. The stent of claim 23, wherein the first expansion strut column, the second expansion strut column and the first connecting strut column form a plurality of geometric configurations and at least a portion of the plurality form asymmetrical geometric configurations.

29. The stent of claim 23, wherein the first expansion strut column, the second expansion strut column and the first connecting strut column form a plurality of geometric configurations and at least a portion of the plurality form asymmetrical geometric configurations.

30. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the first corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the first corner of the third expansion strut pair of the second expansion strut column.

31. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the second corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the second corner of the third expansion strut pair of the second expansion strut column.

32. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the first corner of the

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second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the first corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column.

33. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the second corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the second corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column.

34. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the first corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the first corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the first corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the first corner of the third expansion strut pair of the second expansion strut column.

35. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the first corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the second corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the first corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the second corner of the third expansion strut pair of the second expansion strut column.

36. The stent of claim 24, wherein the first connecting strut proximal section is coupled to the second corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the first corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the second corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the first corner of the third expansion strut pair of the second expansion strut column.

37. The stent of claim 23, wherein the first connecting strut proximal section is coupled to the second corner of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the second corner of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the second corner of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the second corner of the third expansion strut pair of the second expansion strut column.

38. The stent of claim 23, wherein the first column expansion strut pairs define first column loop slots, and the second column expansion strut pairs define second column loop slots.

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39. The stent of claim 38, wherein the first column loop slots are parallel to the second column loop slots.

40. The stent of claim 38, wherein the first column loop slots are not parallel to the second column loop slots.

41. The stent of claim 38, wherein the first column loop slots are longitudinally offset from the second column loop slots.

42. The stent of claim 38, wherein the first column loop slots are non-collinear to the second column loop slots.

43. The stent of claim 38, wherein the first column loop slots are collinear with the second column loop slots.

44. The stent of claim 38, wherein a width of first column loop slots is the same as a width of second column loop slots.

45. The stent of claim 38, wherein a width of the first column loop slots is different than a width of the second column loop slots.

46. The stent of claim 38, wherein a shape of the first column loop slots is different than a shape of the second column loop slots.

47. The stent of claim 38, wherein a shape of the first column loop slots is the same as a shape of the second column loop slots.

48. The stent of claim 38, wherein a shape of a first column loop slot of the first expansion column is different from a shape of an adjacent first column loop slot of the first expansion column.

49. The stent of claim 38, wherein a shape of a first column loop slot of the first expansion column is the same as a shape of an adjacent first column loop slot of the first expansion column.

50. The stent of claim 38, wherein a width of a first column loop slot of the first expansion column is different from a width of an adjacent first column loop slot of the first expansion column.

51. The stent of claim 38, wherein a width of a first column loop slot of the first expansion column is the same as a width of an adjacent first column loop slot of the first expansion column.

52. The stent of claim 23, wherein each connecting strut proximal section has a substantially linear geometry.

53. The stent of claim 52, wherein each connecting strut distal section has a substantially linear geometry.

54. The stent of claim 53, wherein each connecting strut intermediate section has a substantially linear geometry.

55. The stent of claim 23, wherein a ratio of a number of expansion struts in an expansion strut column to a number of connecting struts in a connecting strut column is 2 to 1.

56. The stent of claim 23, wherein the stent includes m first and second expansion columns, n connecting struts per column and $n(m-1)/2$ connecting struts.

57. The stent of claim 23, wherein the first and second expansion columns are each unbroken, continuous column structures.

58. The stent of claim 23, wherein one of the first or second expansion column is a broken column structure.

59. The stent of claim 23, further comprising:

a plurality of first expansion columns;

a plurality of second expansion columns; and

a plurality of first connecting strut columns, each first connecting strut column coupling a first expansion column to a second expansion column.

60. The stent of claim 59, wherein a plurality of first expansion columns, second expansion columns and first connecting strut columns form a continuous a chain mesh strut frame pattern.

61. The stent of claim 59, wherein the plurality of first expansion columns, the plurality of second expansion col-

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umns and the plurality of first connecting strut columns form an elongated structure.

62. The stent of claim 23, further comprising:

a reinforcement expansion column made of a plurality of reinforcement expansion struts, wherein each reinforcement expansion strut has a width that is greater than a width of an expansion strut in the first or second expansion columns.

63. The stent of claim 23, wherein the stent has a proximal end with a first reinforcement expansion column and a distal end with a second reinforcement expansion column.

64. The stent of claim 23, wherein the stent has a reinforcement expansion column between a proximal end and a distal end of the stent.

65. The stent of claim 23, further comprising:

a third expansion column formed of a plurality of third expansion column strut pairs, a first expansion strut pair including a first expansion strut adjacent to a second expansion strut and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, a second expansion strut pair including a third expansion strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third expansion strut pair including a fourth expansion strut adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a fourth expansion strut pair including a fifth expansion strut adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair first corner formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair second corner formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair first corner formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair second corner formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair first corner formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair second corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair second corner formed where the fourth joining strut is coupled to the fifth expansion strut; and

a second connecting strut column formed of a plurality of second connecting struts, each connecting strut of the second connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the second expansion strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the third expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the second expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the third expansion strut column.

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66. The stent of claim 65, wherein the first expansion strut of the first expansion strut pair in the second expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the third expansion column.

67. The stent of claim 65, wherein the first expansion column, the second expansion column, and the first connecting strut column form a first plurality of geometric cells, and the second expansion column, the third expansion column and the second connecting strut column form a second plurality of geometric cells.

68. The stent of claim 68, wherein at least a portion of the first plurality of geometric cells and at least a portion of the second plurality of geometric cells form asymmetric cells.

69. The stent of claim 67, wherein at least a portion of the first plurality of geometric cells and at least a portion of the second plurality of geometric cells are symmetric cells.

70. The stent of claim 67, wherein each geometric cell of the first plurality includes a proximal looped slot and a distal looped slot, and each geometric cell of the second plurality includes a proximal looped slot and a distal looped slot.

71. The stent of claim 70, wherein each distal looped slot of a cell of the first plurality is juxtapositioned to a corresponding proximal looped slot of a cell of the second plurality.

72. The stent of claim 65, wherein the stent includes a proximal expansion column, a distal expansion column, a plurality of connecting struts positioned between the proximal and distal expansion columns, and a plurality of expansion columns positioned between the proximal and distal expansion columns, each expansion column being made of a plurality of juxtapositioned proximal and distal looped slots.

73. The stent of claim 23, wherein a width of the first connecting strut is equal to or less than a width of the first expansion strut of the first or second expansion columns.

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74. The stent of claim 23, wherein a width of a connecting strut of the first connecting strut column is larger than a width of a first expansion strut of the first or second expansion columns.

75. The stent of claim 23, wherein a width of the second expansion strut of the first or second expansion columns is substantially the same as the width of the first expansion strut of the first or second expansion columns.

76. The stent of claim 23, wherein the stent has a tapered diameter in an expanded state.

77. The stent of claim 23, wherein the stent has a tapered geometry extending from a proximal end to a distal end in an expanded state.

78. The stent of claim 23, wherein the stent is configured to be positioned at an exterior of an expandable balloon.

79. The stent assembly of claim 78, wherein the balloon is curved extending from a proximal end and a distal end in an expanded state.

80. The stent assembly of claim 79, wherein the balloon is tapered in an expanded state and the stent has a non-tapered geometry in an expanded state.

81. The stent assembly of claim 79, wherein the balloon and the stent are both tapered in an expanded state.

82. The stent assembly of claim 79, wherein the stent is non-tapered in an expanded state.

83. The stent assembly of claim 79, wherein the stent is tapered in an expanded state.

84. The stent of claim 79, wherein the stent in an expanded state is non-tapered, and the balloon is tapered and curved in an expanded state.

85. The stent of claim 79, wherein the stent is tapered in an expanded state, and the balloon is tapered and curved in an expanded state.

* * * * *

18-41

CM 000041

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)
)
 Plaintiff,)
)
 v.) Civ. No. 03-027-SLR
)
 BOSTON SCIENTIFIC CORPORATION)
 and SCIMED LIFE SYSTEMS, INC.,)
)
 Defendants.)

MEMORANDUM ORDER

At Wilmington this 31 day of June, 2005, having heard oral argument and having reviewed the papers submitted in connection with the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language in U.S. Patent Nos. 5,895,406 ("the '406 patent"), 5,922,021 ("the '021 patent") and 4,739,762 ("the '762 patent"), as identified by the above referenced parties, shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit, as follows:

A. Claim 1 of the '406 patent.

1. "Stent."

Consistent with the claim language and its ordinary meaning¹ and the specification,² the court construes "stent" to mean "a tubular structure left inside a vessel to hold the vessel open."

2. "Comprising."

The court finds that "comprising" is a term of art that means "the named elements are essential, but other elements may be added and still form a [device] within the scope of the claim."³

3. "Longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis."

Consistent with the claim language and its ordinary meaning, the specification⁴ and the prosecution history,⁵ the court

¹See Stedman's Medical Dictionary 1336 (27th ed. 2002) (defining "stent" as a device "to assure patency of an intact but contracted lumen").

²'406 patent, col. 1, ll. 16-17; *Id.*, col. 3, ll. 28-32.

³*Stifung v. Renishaw PLC*, 945 F.2d 1173 (Fed. Cir. 1991); see also *Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000). Elements that are otherwise excluded by the prosecution history or an explicit claim limitation are not claimed. See *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001); *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1379-80 (Fed. Cir. 1998).

⁴Claim 1 requires that there be a plurality of links between bands. ('406 patent, col. 5, l. 32) The specification requires that the bands undulate through approximately two cycles before there is a circumferential link and that there be a plurality of periodic links. ('406 patent, col. 4, ll. 7-10, 15-17) Nowhere in the patent does it direct one of ordinary skill in the art how

construes this limitation to mean that "the stent has multiple elongated surfaces that run parallel to the stent's long axis, each of these surfaces having the undulating appearance of a continuous wave."

5. "Links."

Consistent with the claim language and its ordinary meaning,⁶ the specification⁷ and the prosecution history,⁸ the court construes "links" to mean "short separate structures that run transverse to the long axis of the stent in order to connect adjacent longitudinal bands."

6. "Axial flexibility."

to construct a stent that meets these criteria without the bands running the length of the stent. Figures 3(a) and (b), showing a "portion of a stent with two bands between two circumferential links," cannot mean that a band is only what is shown, as what is depicted does not have a plurality of links. (See also '406 patent, col. 2, ll. 52-59 (describing Fig. 1(c) and (d) as an "axially flexible stent in accordance with present invention")) This construction does not read into the independent claim the limitations for its dependent claims, as none of the dependent claims cited by Cordis requires that the bands run the length of the stent. (See '406 patent, claim 10 and claim 17 (requiring that the bands be capped at the ends of the stent); Id., claim 3 (requiring that the band change in spatial frequency along its length))

⁵D.I. 230, Ex. 37 at 11637; Id., Ex. 34.

⁶D.I. 230, Ex. 39 (defining "link" as "a piece or part . . . that holds two or more important elements together . . .").

⁷'406 patent, col. 4, ll. 15-17.

⁸D.I. 230, Ex. 40 at 5, 6; D.I. 280, Ex. 42 at BSC11646.

Consistent with the claim language and its ordinary meaning⁹ and the specification,¹⁰ the court construes "axial flexibility" to mean "can bend or flex along its length."

B. Claim 12 of the '406 patent.

1. "Spatially aligned so as to be generally in phase with one another."

Consistent with the claim language and its ordinary meaning¹¹ and the specification,¹² the court construes this limitation to mean "the bands generally undulate at the same rate, so as to run parallel to each other."

C. Claim 23 of the '021 patent.

1. "Strut."

⁹D.I. 230, Ex. 41 (defining "axial" as "[l]ocated on, around, or in the direction of an axis" and "flexible" as "[c]apable of being bent or flexed").

¹⁰Claim 1 refers to both a longitudinal axis, parallel to which the bands run, and a circumferential axis on which the connecting links are placed. The specification, however, refers to the links as providing stability, not flexibility. ('406 patent, col. 4, ll. 58-61; col. 3, ll. 48-50) Therefore, a reference to axial flexibility must be referring to longitudinal flexibility.

¹¹D.I. 230, Ex. 41 (defining "align" as "[t]o arrange in a line or so as to be parallel"); D.I. 280, Ex. 10 (defining "in phase" as "in a synchronized or correlated manner").

¹²'406 patent, col. 4, ll. 10-15.

Consistent with the claim language and its ordinary meaning,¹³ this court construes "strut" to mean "a structural member designed to withstand force."

2. "Expansion strut pair corners" and "corners" of "expansion strut pairs."

Consistent with the claim language and its ordinary meaning¹⁴ and the specification,¹⁵ this court construes "corners" to mean "a place where two surfaces meet to form an angle."

3. "A first connecting strut column formed of a plurality of first connecting struts."

Consistent with the claim language and its ordinary meaning¹⁶ and the specification¹⁷ this court construes this

¹³D.I. 230, Ex. 4 (defining "strut" as "[a] structural member which is designed to take compression").

Cordis argues that the strut is designed to withstand pressure along its length. The specification, however, indicates that the stent is designed to withstand radial forces; limiting "strut" to structures that withstand pressure along their length is too narrow. ('021 patent, col. 3, ll. 24, 26, 46-47)

¹⁴D.I. 230, Ex. 5 at 452 (defining "corner" as "the place at which two converging lines or surfaces meet" and "the space between two converging lines or surfaces near their intersection; angle"); D.I. 233, Ex. 11 at 507 (defining "corner" as "the point or place where converging lines, edges or sides meet: ANGLE . . .").

¹⁵'021 patent, col. 11, ll. 66-67 - col. 12, ll. 11.

¹⁶BSC argues that this limitation should be construed simply as a "column . . . formed of connecting struts." This construction, however, is not consistent with the other claims. (See, e.g., '021 patent, col. 18, ll. 24-31; '021 patent, col. 22, ll. 42-52) (referring to "first connecting strut" as connecting the first expansion strut pair and second expansion

limitation to mean "a column formed of at least two first connecting struts."

4. "Wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column."

Consistent with the claim language and its ordinary meaning and the specification¹⁸ and prosecution history,¹⁹ this court construes this limitation as meaning that "the first expansion strut in the first column does not share a longitudinal axis with the second expansion strut in the second column."

D. Claim 1 of the '762 patent.

1. "Comprising."

strut pair). Without a clear indication in the specification that "first connecting struts" should be given a different meaning in different claims, it should be construed consistently throughout. See also, Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Inter'l, Inc., 389 F.3d 1370, 1377 (Fed. Cir. 2004) (citation omitted). Thus, this court declines to adopt BSC's asserted construction of this limitation.

¹⁷'021 patent, col. 6, ll. 46-52 (defining the "first connecting strut" as the first strut in the column and "second connecting strut" as the second strut in the column).

¹⁸'021 patent, col. 6, ll. 53-55 (defining "offset" as not collinear).

¹⁹D.I. 233, Ex. 25 at JFH 192, 196, 209, 217.

The court finds that "comprising" is a term of art that means "the named elements are essential, but other elements may be added and still form a [device] within the scope of the claim."²⁰

2. "Thin-walled."

Consistent with the court's previous construction,²¹ "thin-walled" is construed to mean "the wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters."

3. "The slots being disposed substantially parallel to the longitudinal axis of the tubular member."

Consistent with the claim language and its ordinary meaning²² and this court's previous construction,²³ this court

²⁰Stifung v. Renishaw PLC, 945 F.2d 1173 (Fed. Cir. 1991); see also Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1382 (Fed. Cir. 2000). Elements that are otherwise excluded by the prosecution history or an explicit claim limitation are not claimed. See Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001); Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1379-80 (Fed. Cir. 1998).

²¹Cordis Corp. v. Medtronic AVE, Inc., 194 F. Supp.2d 323, 332 (D. Del. 2002).

²²Cordis Corp., 339 F.3d at 1360 ("'substantially' as used in this context, denotes approximation.")

²³ In 97-550-SLR the court construed "plurality of slots" in such a way as to include the "substantially parallel" limitation. (97-550-SLR, D.I. 1127) The court includes this previous construction to make it clear what the limitation as a whole is construed to mean.

construes this limitation to mean that "a 'slot' is a long and narrow opening or groove, an opening whose length is substantially greater than its width. The claim requires slots in the tubular members that run largely or approximately parallel to the longitudinal axis."

E. Claim 9 of the '762 patent.

1. "Thin-walled."

Consistent with the construction of "thin-walled" for claim 1 of the '762 patent, the court construes "thin-walled" to mean "the wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters."

2. "Biologically inert coating."

Consistent with the claim language and its ordinary meaning²⁴ and the prosecution history,²⁵ this court construes "biologically inert coating" to mean "a coating that is not biologically active."

F. Claim 13 of the '762 patent.

1. "Comprising."

²⁴D.I. 233, Ex. 6 at col. 4, ll. 44-48 (referring to "inert and antithrombogenic outer surface."); Stedman's Medical Dictionary 706 (5th ed. 1982) (defining "inert" as "[i]nactive" or "[h]aving no pharmacologic or therapeutic action").

²⁵D.I. 233, Ex. 8 and PWRAP 3010 (indicating that at the time of the invention, it was known that something could be biologically inert and reduce thrombogenicity).

The court finds that "comprising" is a term of art that means "the named elements are essential, but other elements may be added and still form a [device] within the scope of the claim."²⁶

2. "Thin-walled."

Consistent with the construction of "thin-walled" for claim 1 of the '762 patent, the court construes "thin-walled" to mean "the wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters."

3. "Substantially uniform thickness."

Consistent with this court's previous construction²⁷ and the Federal Circuit's review of that construction,²⁸ "substantially uniform thickness" is construed to mean "the wall of the tubular member must be of largely or approximately uniform

²⁶Stifung v. Renishaw PLC, 945 F.2d 1173 (Fed. Cir. 1991); see also Vehicular Technologies Corp. v. Titan Wheel Int'l, Inc., 212 F.3d 1377, 1382 (Fed. Cir. 2000). Elements that are otherwise excluded by the prosecution history or an explicit claim limitation are not claimed. See Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001); Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1379-80 (Fed. Cir. 1998).

²⁷Id.

²⁸This court does not view the Federal Circuit's 2003 opinion as reversing its original construction of "substantially uniform thickness," but instead clarifying the scope of that construction. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1360-62 (Fed. Cir. 2003). Thus, this court does not agree with BSC that the Federal Circuit's opinion added to the limitation that the stent must allow for "uniform expansion."

thickness. A wall that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness.

4. "The slots being disposed substantially parallel to the longitudinal axis of the tubular member."

Consistent with the construction of "substantially parallel" for claim 1 of the '762 patent, the court construes "substantially parallel" to mean that "a 'slot' is a long and narrow opening or groove, an opening whose length is substantially greater than its width. The claim requires slots in the tubular members that run largely or approximately parallel to the longitudinal axis."

G. Claim 19 of the '762 patent.

1. "Biologically inert coating."

Consistent with the construction of "biologically inert coating" for claim 9 of the '762 patent, the court construes "biologically inert coating" to mean "a coating that is not biologically active."


United States District Judge

EXHIBIT 3

Downloaded By: John S Fitzgerald

Company: JOHNSON & JOHNSON
Form Type: 8-K SEC File #: 001-03215
Document Type: EX-99
Description: PRESS RELEASE
File Date: 11/17/06
State of Incorporation: NJ
Fiscal Year End: 12/31
CIK: 0000200406
SIC: 2834
IRS Identifying Number: 221024240
JNJ (NY)

Business Address
ONE JOHNSON & JOHNSON PLZ
NEW BRUNSWICK, NJ 08933
732-524-2455

Mailing Address
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Exhibit 99.1

Johnson & Johnson Announces Definitive Agreement to Acquire Conor Medsystems, Inc.

Conor Medsystems to Complement Cordis' Drug-Eluting Stent Capabilities with Unique Controlled Drug Delivery Technology

NEW BRUNSWICK, N.J., and MENLO PARK, CALIF. (November 16, 2006) -- Johnson & Johnson (NYSE: JNJ) and Conor Medsystems, Inc. (NASDAQ: CONR), a cardiovascular device company, today announced a definitive agreement whereby Johnson & Johnson will acquire Conor Medsystems for approximately \$1.4 billion.

The acquisition of Conor Medsystems by Johnson & Johnson will provide Cordis Corporation, a Johnson & Johnson company, with a unique controlled drug delivery technology. This technology is currently employed on the CoStar* Stent System, a paclitaxel-eluting cobalt chromium stent with a bioabsorbable polymer. The CoStar* Stent is currently sold outside the United States, and enrollment in its U.S. pivotal clinical trial has been completed.

Under the terms of the agreement, an all cash merger transaction, Conor Medsystems stockholders will receive at closing \$33.50 for each outstanding Conor Medsystems share. The \$1.3 billion estimated net value of the transaction is based on Conor Medsystem's 42.7 million fully diluted shares outstanding, net of estimated cash on hand at time of closing.

The boards of directors of Johnson & Johnson and Conor Medsystems have approved the transaction, which is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act, Conor Medsystems stockholder approval and other customary closing conditions. The transaction is expected to close in the first quarter of 2007.

Nicholas J. Valeriani, Johnson & Johnson Worldwide Chairman, Cardiovascular Devices and Diagnostics, said, "The addition of Conor Medsystems to the Johnson & Johnson Family of Companies reaffirms our strong commitment to patients with cardiovascular disease and the physicians who treat them."

He continued, "Cordis led the transformation of the treatment of coronary artery disease with the introduction of the first coronary stent, and later reinvented the category with the creation of the CYPHER* Sirolimus-Eluting Stent. With Conor Medsystems, we are positioned to lead the development of next generation technologies aimed at advancing the standard of care in the treatment of coronary artery disease."

Conor Medsystem's CoStar* stent, which provides for drug elution from a stent with a fully bioabsorbable

polymer, employs a unique reservoir drug-delivery technology. These reservoirs enable site-specific drug delivery as well as the potential for delivery of multiple therapeutic agents that may be useful in the treatment of cardiovascular, peripheral vascular and neurovascular diseases. The technology also has potential in other non-vascular clinical indications.

Conor Medsystems will operate as part of the Cordis franchise, the global leader in drug-eluting stents for the treatment of coronary artery disease.

Rick Anderson, Johnson & Johnson Company Group Chairman with responsibility for the Cordis business, said:

"Cordis is looking forward to strengthening its portfolio with the addition of the CoStar* Stent System. We will offer physicians and the patients they treat the most comprehensive portfolio of stents, therapeutic agents, delivery platforms and polymers. By combining the unique capabilities of Conor Medsystems and Cordis, we are confident that we will bring innovative solutions to patients around the world."

Conor Medsystems Chairman and Chief Executive Officer Frank Litvack, M.D., said: "This transaction couples our highly competitive technology platform with the resources of the world's leading health care company. We believe it is clearly in the best interest of Conor Medsystem stockholders and of patients worldwide who seek treatment for vascular disease. Cordis, which created the drug-eluting stent category, is the ideal partner to maximize the potential of our strong technology portfolio, and to accelerate the adoption of this important technology."

Upon closing, Johnson & Johnson is expected to incur an estimated one-time after-tax charge of approximately \$600 million, reflecting the write-off of in-process research and development charges (IPR&D). Excluding IPR&D, the acquisition is expected to be modestly dilutive to Johnson & Johnson's earnings per share in 2007. Additional commentary regarding the financial impact will be discussed during the conference call noted below.

Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical, and medical devices and diagnostics markets. The more than 230 Johnson & Johnson operating companies employ approximately 115,700 men and women in 57 countries and sell products throughout the world.

Conor Medsystems develops innovative controlled vascular drug delivery technologies, and has primarily focused on the development of drug-eluting stents to treat coronary artery disease. For further information on Conor Medsystems and controlled vascular delivery, visit www.conormed.com <<http://www.conormed.com>>.

The CoStar* stent is not available for sale in the United States where it is an investigational device limited by law to investigational use.

NOTE TO INVESTORS

Johnson & Johnson and Conor Medsystems, Inc. will conduct a conference call with financial analysts to discuss this news release on November 17, 2006, at 8:30 a.m., Eastern Standard Time. A simultaneous webcast of the call for interested investors and others may be accessed by visiting the Johnson & Johnson website at www.jnj.com <<http://www.jnj.com> and clicking on "Webcasts/Presentations" in the Investor Relations section or by visiting the Conor Medsystems website at www.conormed.com and clicking on "Webcasts" in the Company section.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Johnson & Johnson's and Conor Medsystem's expectations and projections. Risks and uncertainties include satisfaction of closing conditions including receipt of regulatory approvals for the transaction, and the possibility that the transaction will not be completed; general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2006 and Conor Medsystem's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006. These filings, as well as subsequent filings, are available online at www.sec.gov or on request from the applicable company. Neither company undertakes to update any forward-looking statements as a result of new information or future events or developments.)

Additional Information About the Proposed Transaction and Where To Find It

In connection with the proposed transaction, Conor Medsystems intends to file a proxy statement and other relevant materials with the Securities and Exchange Commission (the "SEC"). Before making any voting decision with respect to the proposed transaction, stockholders of Conor Medsystems are urged to read the

proxy statement and other relevant materials because they will contain important information about the proposed transaction. The proxy statement and other relevant materials, and any other documents filed by Conor Medsystems with the SEC, may be obtained free of charge at the SEC's website at www.sec.gov <<http://www.sec.gov>>. In addition, stockholders of Conor Medsystems may obtain free copies of the documents filed with the SEC by contacting Conor Medsystems at (650) 614-4100, or Conor Medsystems, Inc., 1003 Hamilton Court, Menlo Park, CA 94025. You may also read and copy any reports, statements, and other information filed by Conor Medsystems with the SEC at the SEC public reference room at 100 F Street, NE, Room 1580, Washington, DC 20049. Please call the SEC at 1-800-SEC-0330 or visit the SEC's website for further information on its public reference room.

Conor Medsystems and Johnson & Johnson and each of their executive officers and directors may be deemed to be participants in the solicitation of proxies from Conor Medsystems' stockholders in favor of the proposed transaction. A list of the names of Conor Medsystems' executive officers and directors and a description of their respective interests in Conor Medsystems, are set forth in the proxy statement for Conor Medsystems' 2006 Annual Meeting of Stockholders, which was filed with the SEC on April 28, 2006, and in any documents subsequently filed by its directors and executive officers under the Securities and Exchange Act of 1934, as amended. Certain executive officers and directors of Conor Medsystems have interests in the proposed transaction that may differ from the interests of stockholders generally, including benefits conferred under retention, severance and change in control arrangements and continuation of director and officer insurance and indemnification. These interests and any additional benefits in connection with the proposed transaction will be described in the proxy statement when it becomes available.

*Cordis Corporation has entered into an exclusive worldwide license with Wyeth for the localized delivery of sirolimus in certain fields of use, including delivery via vascular stenting. Sirolimus, the active drug released for the stent, is marketed by Wyeth Pharmaceuticals, a division of Wyeth, under the name Rapamuner. Rapamune is a trademark of Wyeth Pharmaceuticals.

#

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Company: JOHNSON & JOHNSON
Form Type: 8-K SEC File #: 001-03215
Document Type: EX-99
Description: TRANSCRIPT
File Date: 11/17/06
State of Incorporation: NJ
Fiscal Year End: 12/31
CIK: 0000200406
SIC: 2834
IRS Identifying Number: 221024240
JNJ (NY)

Business Address
ONE JOHNSON & JOHNSON PLZ
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732-524-2455

Mailing Address
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EXHIBIT 4

Delaware

PAGE 1

The First State

I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED ARE TRUE AND CORRECT COPIES OF ALL DOCUMENTS FILED FROM AND INCLUDING THE RESTATED CERTIFICATE OR A MERGER WITH A RESTATED CERTIFICATE ATTACHED OF "CONOR MEDSYSTEMS, LLC" AS RECEIVED AND FILED IN THIS OFFICE.

THE FOLLOWING DOCUMENTS HAVE BEEN CERTIFIED:

CERTIFICATE OF MERGER, FILED THE FIRST DAY OF FEBRUARY, A.D. 2007, AT 12:40 O'CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE FIRST DAY OF FEBRUARY, A.D. 2007, AT 4:01 O'CLOCK P.M.

CERTIFICATE OF CONVERSION, CHANGING ITS NAME FROM "CONOR MEDSYSTEMS, INC." TO "CONOR MEDSYSTEMS, LLC", FILED THE FIFTH DAY OF MARCH, A.D. 2007, AT 4:14 O'CLOCK P.M.

CERTIFICATE OF FORMATION, FILED THE FIFTH DAY OF MARCH, A.D. 2007, AT 4:14 O'CLOCK P.M.

3114219 8100X
070325709



Harriet Smith Windsor
Harriet Smith Windsor, Secretary of State
AUTHENTICATION: 5512191

DATE: 03-16-07

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:40 PM 02/01/2007
FILED 12:40 PM 02/01/2007
SRV 070113215 - 3114219 FILE

CERTIFICATE OF MERGER
MERGING
CYPRESS ACQUISITION SUB, INC.
WITH AND INTO
CONOR MEDSYSTEMS, INC.

Pursuant to Section 251 of the General Corporation Law of the State of Delaware (the "DGCL"), Conor Medsystems, Inc., a Delaware corporation (the "Corporation"), hereby certifies as follows:

FIRST: The name and state of incorporation of each of the constituent corporations to the merger (the "Constituent Corporations") are as follows:

<u>Name</u>	<u>State of Incorporation</u>
Cypress Acquisition Sub, Inc.	Delaware
Conor Medsystems, Inc.	Delaware

SECOND: Cypress Acquisition Sub, Inc. is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation ("Parent"). The Agreement and Plan of Merger dated as of November 16, 2006 (the "Merger Agreement"), among Parent and each of the Constituent Corporations, has been approved, adopted, certified, executed and acknowledged by each of the Constituent Corporations in accordance with Section 251 of the DGCL.

THIRD: The Corporation shall be the surviving corporation after the merger (the "Surviving Corporation"). The name of the Surviving Corporation shall be Conor Medsystems, Inc.

2

FOURTH: The Amended and Restated Certificate of Incorporation of the Corporation, as in effect immediately prior to the Effective Time (as defined below), shall be amended at the Effective Time as set forth in Exhibit A attached hereto, and, as so amended, such Amended and Restated Certificate of Incorporation shall be the Amended and Restated Certificate of Incorporation of the Surviving Corporation until thereafter changed or amended as provided therein or by applicable law.

FIFTH: The executed Merger Agreement is on file at the office of the Surviving Corporation, located at 1003 Hamilton Court, Menlo Park, CA 94025.

SIXTH: A copy of the Merger Agreement will be furnished by the Surviving Corporation, on request and without cost, to any stockholder of either Constituent Corporation.

SEVENTH: This Certificate of Merger, and the merger provided for herein, shall become effective at 4:01 P.M. Eastern Standard Time on the date this Certificate of Merger is filed with the Secretary of State of the State of Delaware (the "Effective Time").

This Certificate of Merger has been executed on this 1st day of February, 2007.

CONOR MEDSYSTEMS, INC.,

by

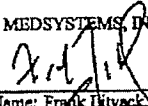

Name: Frank Litvack, M.D.
Title: Chairman & Chief Executive Officer

EXHIBIT A
TO THE CERTIFICATE OF MERGER

Amended and Restated Certificate of Incorporation
of Conor Medsystems, Inc.

FIRST: The name of the corporation (hereinafter called the "Corporation") is CONOR MEDSYSTEMS, INC.

SECOND: The address, including street, number, city, and county, of the registered office of the Corporation in the State of Delaware is Corporate Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, County of New Castle; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The aggregate number of shares which the Corporation shall have authority to issue is 1,000 shares of Common Stock, par value \$0.01 per share.

FIFTH: In furtherance and not in limitation of the powers conferred upon it by law, the Board of Directors of the Corporation is expressly authorized to adopt, amend or repeal the Bylaws of the Corporation.

SIXTH: To the fullest extent permitted by the General Corporation Law of the State of Delaware as it now exists and as it may hereafter be amended, no director or officer of the Corporation shall be personally liable to the Corporation or any of its stockholders for monetary damages for breach of fiduciary duty as a director or officer; provided, however, that nothing contained in this Article SIXTH shall eliminate or limit the liability of a director or officer (i) for any breach of the director's or officer's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the General Corporation Law of the State of Delaware or (iv) for any transaction from which the director or officer derived an improper personal benefit. No amendment to or repeal of this Article SIXTH shall apply to or have any effect on the liability or alleged liability of any director or officer of the Corporation for or with respect to any acts or omissions of such director or officer occurring prior to such amendment or repeal.

SEVENTH: The Corporation shall, to the fullest extent permitted by Section 145 of the General Corporation Law of the State of Delaware, as the same may be amended and supplemented, indemnify any and all persons whom it shall have power to indemnify under said Section from and against any and all of the expenses, liabilities, or other matters referred to in or covered by said Section. Such indemnification shall be mandatory and not discretionary. The indemnification provided for herein shall not be

deemed exclusive of any other rights to which those indemnified may be entitled under any by-law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his or her official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such a person. Any repeal or modification of this Article SEVENTH shall not adversely affect any right to indemnification of any persons existing at the time of such repeal or modification with respect to any matter occurring prior to such repeal or modification.

The Corporation shall to the fullest extent permitted by the General Corporation Law of the State of Delaware advance all costs and expenses (including, without limitation, attorneys' fees and expenses) incurred by any director or officer within 15 days of the presentation of same to the Corporation, with respect to any one or more actions, suits or proceedings, whether civil, criminal, administrative or investigative, so long as the Corporation receives from the director or officer an unsecured undertaking to repay such expenses if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Corporation under the General Corporation Law of the State of Delaware. Such obligation to advance costs and expenses shall be mandatory, and not discretionary, and shall include, without limitation, costs and expenses incurred in asserting affirmative defenses, counterclaims and cross claims. Such undertaking to repay may, if first requested in writing by the applicable director or officer, be on behalf of (rather than by) such director or officer, provided that in such case the Corporation shall have the right to approve the party making such undertaking.

EIGHTH: Unless and except to the extent that the Bylaws of the Corporation shall so require, the election of directors of the Corporation need not be by written ballot.

FROM CORPORATION TRUST 302-655-2480

(MON) 3. 5' 07 10:52/ST.10:51/NO.4862069430 P 2

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:14 PM 03/05/2007
FILED 04:14 PM 03/05/2007
SRV 070280350 - 3114219 FILE

STATE OF DELAWARE
CERTIFICATE OF CONVERSION
FROM A CORPORATION TO A
LIMITED LIABILITY COMPANY PURSUANT TO
SECTION 18-214 OF THE LIMITED LIABILITY ACT

- 1.) The jurisdiction where the Corporation first formed is Delaware.
- 2.) The jurisdiction immediately prior to filing this Certificate is Delaware.
- 3.) The date the corporation first formed is October 25, 1999.
- 4.) The name of the Corporation immediately prior to filing this Certificate is
Conor Medsystems, Inc.
- 5.) The name of the Limited Liability Company as set forth in the Certificate of
Formation is Conor Medsystems, LLC

IN WITNESS WHEREOF, the undersigned have executed this Certificate on the
5th day of March, A.D. 2007.

By: Steven M. Rosenberg
Authorized Person

Name: Steven M. Rosenberg
Print or Type

FROM CORPORATION TRUST 302-655-2480

(MON) 3. 5' 07 10:52/ST. 10:51/NO. 4862069430 P 3

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:14 PM 03/05/2007
FILED 04:14 PM 03/05/2007
SRV 070280350 - 3114219 FILE


CERTIFICATE OF FORMATION

OF

CONOR MEDSYSTEMS, LLC

1. The name of the limited liability company is Conor Medsystems, LLC.
2. The address of its registered office in the State of Delaware is: Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.
3. To the fullest extent that the laws of the State of Formation, as they exist on the date hereof or as they may hereafter be amended, permit the limitation or elimination of the liability of officers, no officer of the Company shall be personally liable to the Company or its Member for damages for breach of any duty owed to the Company. Neither the amendment or repeal of this provision nor the adoption of any provision of this Certificate of Formation which is inconsistent with this provision shall apply to or have any effect on the liability or alleged liability of any officer of the Company for or with respect to any act or omission of such officer occurring prior to such amendment, repeal or adoption.

IN WITNESS WHEREOF, the undersigned have executed this Certificate of Formation of Conor Medsystems, LLC this 5th day of March, 2007.


Steven M. Rosenberg, Authorized Person